Southern District Health Board

A Report by the

Health and Disability Commissioner

(Case 16HDC01010)

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Executive summary

1. On 14 July 2014, Mr A, presented to the Hospital 1 Ophthalmology (Eye) Service. Mr A had been referred urgently by a community optometrist. Mr A had a family history of glaucoma. He was prescribed eye drops and a follow-up review went ahead on 21 July 2014. On 16 September 2014, at a further scheduled appointment, Mr A was diagnosed with ocular hypertension. The consultant requested that Mr A be seen again in six months' time in approximately March 2015.

2. However, Mr A's follow-up appointment was delayed by six months. By the time he was seen on 9 September 2015, Mr A had suffered vision loss in his right eye and he required an urgent referral to Hospital 2 for management and surgery.

Findings summary

3. Southern DHB (SDHB) failed to arrange a timely follow-up appointment for Mr A because SDHB did not have a prioritisation system that focused on patients' clinical need, and instead relied on administration staff who lacked training and clear guidance to prioritise appropriately. Despite concerns being raised with SDHB, it did not recognise the clinical risk created by the lack of capacity at the Ophthalmology Service, and did not take action to rectify the situation after a 2014/15 serious event review in relation to a similar matter had raised associated concerns. In addition, there were missed opportunities for SDHB to rectify the delay in Mr A's follow-up appointment. SDHB did not provide services to Mr A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

4. The Commissioner was mindful, as detailed in a thorough external review of the Ophthalmology Service commissioned by SDHB, of a combination of factors that have driven rapidly increasing demand for ophthalmology services in New Zealand, including outpatient clinic time, over the last 10 years. A key factor has been the introduction of very effective new therapies and treatment, which have resulted in consumers needing to see specialists for regular ongoing follow-up and/or treatment, fuelling increased demand for ophthalmology services. The Commissioner considers that the Ministry of Health has a role, with DHBs, to recognise the effect of the introduction of such new technologies and associated pressures on the system, and plan accordingly.

5. The Commissioner commented that provider accountability is not removed by the existence of systemic pressures, and that a key improvement that all DHBs and the Ministry of Health must make, now and in the future, is to assess, plan, adapt, and respond effectively to the foreseeable effects that new technologies will have on systems and demand.

6. Following on from the external review, and the ongoing work of DHBs and the Ministry of Health to address this issue, the Commissioner made a series of detailed recommendations requesting follow-up information and evidence of the effectiveness of corrective actions and strategies adopted.

7. SDHB will be referred to the Director of Proceedings for the purpose of deciding whether any proceedings should be taken.

Complaint and investigation

8. The Commissioner received a complaint from Mr A about a delay in follow-up ophthalmology care provided to him by SDHB.

9. The following issue was identified for investigation:

Whether Southern District Health Board provided Mr A with care of an appropriate standard.

10. An investigation was commenced on 20 March 2017.[1]

11. The parties directly referred to in this investigation report are:

Mr A	Consumer, complainant
Ms B	Clinical nurse specialist
Mr C	Community optometrist
Southern District Health Board	Provider
Dr D	Consultant ophthalmologist
Dr E	Consultant ophthalmologist

12. Information from the Ministry of Health was also reviewed.

13. A copy of the 24 March 2017 report, *Review of 34 ophthalmic (eye) incidents in the Southern DHB (SDHB) identified in the period 1 July 2015 to 30 September 2016*, commissioned by SDHB, is attached as **Appendix A**.

Information gathered during investigation

Clinical background

14. On 14 July 2014, Mr A presented to the Hospital 1 Ophthalmology (Eye) Service. Initially he saw an ophthalmology clinical nurse specialist, Ms B.

15. Mr A had been referred to the hospital urgently by a community optometrist, Mr C, who had identified elevated intraocular pressures (40mmHg in each eye)[2] of concern during a routine optometry appointment.

[1] Concurrently the Ministry of Health was alerted to this case.

16. Mr A had a family history of glaucoma[3]. Mr A's work involved driving.

17. SDHB records for 14 July 2014 indicate that Mr A reported frequent headaches, had blurred distance vision, was finding it hard to read, and that he felt "very short sighted".

18. Ms B's resulting clinic letter states that Mr A's visual acuities were 6/9 in each eye,[4] and intraocular pressures were 44mmHg in each eye. Consultant ophthalmologist Dr D prescribed Mr A Cosopt drops,[5] to be used twice daily. A follow-up review was arranged for the following week.

21 July 2014

19. On 21 July 2014, Mr A was seen again by Dr D, who decided to seek clinical input from a fellow SDHB consultant ophthalmologist, Dr E.

20. On 22 August 2014, SDHB received visual field and optical coherence tomography (OCT)[6] data from optometrist Mr C.

16 September 2014 — Dr E appointment

21. On 16 September 2014, at a scheduled appointment with Dr E at Hospital 1, Mr A's intraocular pressures (IOPs) were 16mmHg (R) and 17mmHg (L), which were within accepted normal limits. The IOPs had improved with the use of the Cosopt drops prescribed by Dr D.

22. Mr A was diagnosed with ocular hypertension (with no evidence of pigment dispersion[7]) and the family history of glaucoma was documented in the records. Dr E planned to locate the clinical notes relating to Mr A's father's treatment.[8]

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[2] The Glaucoma Research Foundation states that eye pressure is measured in millimetres of mercury (mmHg). Normal pressure ranges from 12–22mmHg, and pressure of greater than 22mmHg is considered above normal. When the intraocular pressure is higher than normal, without signs of glaucoma, this is referred to as ocular hypertension.

[3] Usually, glaucoma is caused by a build-up of the fluid that flows through the eye. This build-up occurs because the fluid drains out of the eye more slowly than it is pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye, resulting in gradual loss of sight.

[4] The external review explains that visual acuity reflects a comparison against normal vision. The first number is the distance in metres from the chart, to where the patient stands (6m), the second number is how well the patient can read when standing at 6m, compared with a normal person. Thus 6/12 means that a patient standing 6m away from the chart can read only as well as a normal person standing 12m away. Normal vision is 6/6 (previously, in feet, 20/20). 6/12 vision (using both eyes) is required to obtain a licence to drive. The World Health Organization regards vision of 3/60 or worse (both eyes) as "blindness".

[5] Used to lower raised pressure in the eye and to treat glaucoma.

[6] A non-invasive imaging technique using light waves to take a cross section of the retina.

[7] This occurs when pigment granules clog the drainage system that takes fluid away from the eye. Consequently, there is a pressure build-up inside the eye.

[8] Mr A's father had been treated in the past by a private ophthalmologist, and in September 2014 Dr E wrote to him requesting information regarding Mr A's father's treatment. The letter was copied to Mr A's GP.

23. Dr E told HDC:

> "I first reviewed [Mr A] on 16/9/2014, approximately 2 months after he had been seen by [Dr D]. His vision was good with spectacle correction and he was using the Cosopt eye drops as prescribed by [Dr D]. His Intraocular Pressures (IOPs) were well-controlled at 16 and 17mmHg Right and Left respectively. His angles were open to examination and his optic nerves looked healthy with Cup-to-disc Ratios (CDRs)[9] of 0.3 bilaterally. A Follow up interval of 6 months was requested, as this was deemed appropriate for a patient who had no evidence of glaucoma damage and whose IOPs were within normal limits."[10]

24. Dr E hand wrote in his notes, "R/v [six months] (sooner if problems)" — ie, approximately March 2015.

25. In his resulting clinic letter addressed to the referring optometrist, Mr C (and copied to Mr A and his GP), Dr E concluded: "I have asked [Mr A] to continue on Cosopt eye drops and arranged review although I would be happy to see him sooner should there be any concerns."

26. Dr E told HDC:

> "The [Serious Adverse Event Report (SAER)] … has misread my writing; I wrote '(sooner if problems)' not '(sooner if possible)'. I have always written this condition in all my notes and, furthermore, include a statement of 'sooner if concerns' in a copy of all letters pertaining to the patient, and a copy is always (requested by me) to be sent to the patient/carers wherever possible. This is specifically so that the patient knows that they should contact the department for more urgent review if there are appropriate concerns of their treatment/management."

27. At this time, SDHB utilised a clinical outcome sheet record, in addition to the notes of the consultant. In this case,[11] the six-month suggested time frame for the follow-up appointment was transposed on to the clinical outcome sheet, but not the instruction regarding it being sooner if there were any issues.

28. SDHB told HDC that historically the Hospital 1 ophthalmology clinic kept the outcome sheets for all patients for a period of time before they were disposed of later.[12] The practice of disposing of these outcome sheets ceased in January 2015, and all outcome sheets are now kept as part of the patient's clinical record.

[9] The horizontal diameter of the normal optic nerve is approximately 1.5mm. The ratio between the cup and disc diameters is important because acquired optic nerve damage can cause cupping, and increase in the cup/disc ratio.
[10] Dr E points to the International Council of Ophthalmology (ICO) Guidelines for Glaucoma Eye Care as an example.
[11] According to the 2015/16 SAER.
[12] SDHB told HDC that its own investigations (including the 2015/16 SAER) regarding this matter were able to access and review the clinical outcome sheet for Dr E's 16 September 2014 appointment,

Southern DHB's process for follow-up appointments

29. Mr A's requirement for a follow-up appointment in six months' time was entered into the SDHB iPM electronic patient management system appropriately. Booking staff used the "planned appointment" function of the iPM patient management system to manage future follow-up appointments.

30. At the time of Mr A's September 2014 appointment with Dr E, the "Appointment section" of SDHB's "Administrative Procedure Manual"[13] contained the process for Hospital 1 administration staff to use when booking and prioritising follow-up review appointments requested by the clinician.

31. Pages 26 and 27 of the section include the following:

> "**Prioritising Follow-up Patients**
>
> …
>
> There are times when booking a clinic that some patients need to have their time between appointments extended or reduced due to resource demands or visiting consultant timetabling.
>
> The chart below[14] gives an indication of the minimum and maximum length of time that a patient should wait for a follow-up appointment. It is based on 20% of follow-up time.
>
> This is only an indication and the extending of patients to the outer limit must be discussed with the consultant.

Follow-up period	Earliest	Latest
1 week	6 days	8 days
4 weeks	3 weeks	5 weeks
6 weeks	5 weeks	7 weeks
2 months	7 weeks	10 weeks
3 months	11 weeks	4 months
4 months	3 months	5 months
5 months	4 months	6 months
6 months	5 months	8 months
7 months	6 months	9 months
8 months	7 months	10 months
9 months	8 months	12 months

prior to the clinical outcome sheet being disposed of. The clinical outcome sheet was therefore not available to HDC to review.

[13] Southern DHB 70440 V1 Issued 07/03/2013.

[14] The SDHB document references: Cumming, A (ed), *A guide to good practice*, chapter 3, p64. Welsh Assembly Government (2003).

1 year	10 months	16 months
18 months	15 months	22 months
2 years	1 year 9 months	2 years 7 months
3 years	2 years 7 months	3 years 11 months
4 years	3 years 6 months	5 years 4 months
5 years	4 years 4 months	6 years 6 months

…

Booking of Follow-up Appointments

On receipt of instructions to make a follow-up appointment, reappoint from previous appointment for same speciality and clinician.

Requests will be received:

- Following an outpatient clinic.
- As follow-up from an inpatient visit from the ward following discharge.
- From clinician.
- Or other approved source

Send an appointment letter to the patient (standard letter format) …"

Booking administration staff position description

32. The SDHB position description for a Hospital 1 Administration Officer[15] outlines a primary objective of delivering quality administrative and secretarial services, including performance measures listed as being responsible for the preparation of eye outpatient appointments and theatre bookings as required for the Eye Service, and for the administration of referrals, appointments, and surgical waiting lists for the Eye Service.

33. SDHB told HDC that it could not locate any records of training, orientation, or induction material for its Eye Service administration staff.

Administrative structure

34. SDHB told HDC that in 2014 the DHB administration team in Southland, which included Ophthalmology, sat under the direction of a separate management structure from the operational management of the Ophthalmology Department, namely a Service Manager in the Medical Directorate.[16]

[15] Copy provided to HDC. Developed in 2002.

[16] SDHB told HDC that the Service Manager is responsible for service delivery processes, including management of financial performance, activity and production planning, human resource management, quality and risk management, certification and accreditation, clinical pathway development, and other service delivery improvements within the services.

35. SDHB said that the Service Manager for the Surgical Directorate responsible for Ophthalmology understood it to be the administration staff's responsibility to book the patients in to clinic, and believed that the follow-up patients were booked for clinic visits as close to their planned date as possible.

36. SDHB stated:

> "Booking concerns and issues were broadly discussed fortnightly with the Surgical Services Manager and clinical team including the booking staff. Operational day-to-day decision making for booking criteria was not part of this discussion."

Prioritisation

37. The planned appointment list at this time contained large numbers of significantly overdue appointments, which were booked into clinics largely on the basis of those longest overdue.

38. SDHB told ACC in a letter dated 10 June 2016:

> "In 2015 the patient[s] who ha[d] waited the longest for review were booked first …
>
> Due to demand and capacity patients were waiting for review in the ophthalmology clinic longer than their planned follow-up."

Letter from GP

39. Mr A did not receive a six-month follow-up Eye Clinic appointment for March 2015.

40. Mr A's SDHB clinical file contains a letter dated 22 June 2015, from his general practitioner (GP) to the Eye Service at Hospital 1 (date stamp as received by SDHB on 24 June 2015). The letter provided the family history information that had been sought.

41. A handwritten comment, made on 4 August 2015, appears on the SDHB file copy of this letter:

> "4/8/15 ?? why delay
>
> Delayed F/up R/v ≤ 2/12 [review in two months or less]."

42. Dr E stated:

> "I … was the author of the handwritten comment on the letter by [the GP] dated 22/6/2015: My comment was regarding: why there was such a long delay in Receipt of the letter (dated 24 Jun 2015) and my receiving the letter for review (dated 4/8/2015). I noted that [Mr A] had delayed follow-up and therefore [I] requested urgent review in </= 2 months. The letter should then have gone to the Administration staff to make the appointment that I requested."

Telephone calls to the Eye Service

43. Mr A told HDC that when he realised that he was overdue for follow-up, he telephoned the Hospital 1 Eye Service several times. During one of the calls, he reported the pain and blurry vision he was experiencing.

44. SDHB told HDC that no logs of the calls were made by SDHB staff, as no records of telephone calls received by the clinic from patients were kept at that time. It is therefore unclear precisely when Mr A made the contacts with the clinic but, based on later entries in the medical records, it appears to have occurred around August 2015.

45. Mr A told HDC:

> "At that stage the ophthalmology department was still in the main building so I guess I would have just talked to the main office staff that deals with appointments. I'm pretty sure I just rung up and asked how far away they thought my appointment would be and they told me that they were busy and I just had to be patient and wait for a time. So I just left it at that."

46. SDHB told HDC that prior to September 2015, telephone calls to the department were received by administration staff and passed on to clinical staff when deemed appropriate. As the volume of overdue patients increased, it became more difficult to assign patients into available clinic space.

47. Mr A told HDC that at one stage he demanded an appointment. He said:

> "I demanded my appointment about 3 weeks before the 9th of September and I think it was roughly 3–4 months before that I rang to follow up on my appointment time …
>
> The discussion I had was with the office lady, not a doctor, and yes I did demand an appointment. The reason for that was, I was having trouble seeing sometimes and I was having more and more headaches. So basically I rung them up and told them that I thought there was something wrong and I was having trouble seeing and having more and more headaches and if they didn't give me an appointment I was going to come to the hospital and not leave until I was seen. So as you can probably guess they gave me an appointment."

9 September 2015 — vision loss

48. After the above contact, Mr A was seen at an SDHB Eye Service follow-up appointment on 9 September 2015, a year after seeing Dr E in September 2014. This clinical review was approximately six months overdue — double the requested time specified by Dr E.

49. Dr D's resulting clinic letter began by stating:

> "I have reviewed [Mr A] today in regards to his glaucoma. Unfortunately he had a delayed review by six months. He was starting to complain one month ago about some occasional sharp pain in his right eye and fluctuating vision but did

> not really notice any visual loss in his right eye until the eye examination today at the eye department, [Hospital 1]."

50. Dr D noted that Mr A had raised IOP in both eyes (58mmHg right, and 60mmHg left) with some visual loss in the right eye. Dr D's review reported that Mr A's right eye visual acuity had no perception of light (NPL), but his left eye was deemed 6/6 with his glasses in use. His blood pressure was normal at 140/85mmHg.

51. Dr D's impression was that Mr A had iris plateau syndrome[17] in both eyes, causing uncontrolled elevated intraocular pressures. Mr A was given eyedrop medication immediately.

52. Dr D made some handwritten notes of his 9 September 2015 review. The notes feature the comments "… delayed R/V by 6/12 [six months]!" and "NPL!!".

Urgent referral

53. Dr D organised an urgent referral to the Ophthalmology Department at Hospital 2 for control of Mr A's IOP. Dr D hand wrote a referral letter to the Hospital 2 on-call ophthalmology registrar and spoke to a consultant ophthalmologist at Hospital 2.

54. SDHB's Medical Director of Patient Services sent a letter to Mr A dated 14 September 2015. The Medical Director apologised and advised Mr A that an incident had occurred involving his glaucoma follow-up management. The Medical Director said that the event had been reported as an SAC1[18] incident, and indicated that clinical management was being reviewed, and potential recommendations for changes in practice would be proposed.

ACC claim

55. Mr A's GP clinic assisted him to complete an ACC Treatment Injury Claim form, which was signed on 5 October 2015. On 23 June 2016, Mr A was advised that his claim had been accepted.

56. In his report to ACC, Dr E advised:

> "[The loss of vision in Mr A's right eye] can be attributed to the delay in review and therefore probable changes in his treatment … if the rise in intraocular pressure was picked up at the appropriate time (at his six-monthly review) or when he began noticing problems or concerns, then this unfortunate outcome would likely have been avoided."

57. ACC sought advice from an ophthalmologist who provided ACC with the following advice:

[17] A form of glaucoma seen in younger adult patients.
[18] The Severity Assessment Code (SAC) is a numerical rating that defines the severity of an adverse event and, as a consequence, the required level of reporting and investigation to be undertaken for the event.

- Six-monthly follow-up of patients on treatment for high IOPs or established glaucoma is the accepted management norm. The ophthalmologist felt that there was no reason that this should have been extended past six months in this case and, in view of the fact that this was an unusual case by virtue of the early onset very high pressures, a six-month interval before further assessment would be regarded as the maximum time interval for review.

- The failure to identify increasing IOPs in a timely manner has resulted in irreversible loss of neural axons at the level of the optic disc in the right eye — severe glaucomatous damage to the optic nerve.

- It is not possible to state with certainty that the eye pressures would have been starting to go up after a six-month interval but, on the balance of the probabilities, based on the appearance of the optic disc, the ophthalmologist believes that there would have been some indication of pressure increase at that time. He added that when the patient experienced pain in the eye after a further five months, although there was probably considerable visual loss at that stage, there may have been some vision remaining in the right eye that could have been saved if the patient had been seen immediately rather than after a further interval of four weeks.

Hospital 2 inpatient stay

58. Mr A was an inpatient at Hospital 2 from 9 September 2015. Initially his IOP was managed with medications, and his left eye settled, but the IOP in his right eye remained high at 40mmHg.

59. On review by Dr E, Mr A was listed for surgical management of bilateral glaucoma. The primary diagnosis was plateau iris syndrome with bilateral angle closure glaucoma.

60. On 16 September 2015, Mr A underwent a left trabeculectomy[19] (performed under the consultant ophthalmologist at Hospital 2). On 18 September 2015, a right Molteno[20] procedure was performed (under Dr E).

61. On 24 September 2015, Dr E reviewed Mr A (at Hospital 2), and he was discharged with a medication regimen. His IOP remained stable at 8mmHg in both eyes. Subsequently, he was reviewed by Dr E at Hospital 1 at regular intervals.

Subsequent events

Relevance of SDHB 2014/15 SAER (Avastin)

62. In the period overlapping Mr A's care, a Serious Adverse Event Review[21] (SAER) was commenced in October 2014 and completed in January 2015. It identified incidents of vision loss in five Southland consumers. The review was not in relation to patients treated for glaucoma (such as Mr A), but in relation to those experiencing

[19] Trabeculectomy is a surgical procedure used in the treatment of glaucoma to relieve intraocular pressure.
[20] A glaucoma drainage procedure.
[21] Conducted by a nursing director and a consultant ophthalmologist.

delays in Avastin[22] treatment for the condition of age-related macular degeneration[23] (ARMD, see below). The five SAC2 incidents examined by the SAER occurred between 3 July 2014 and 24 September 2014.

63. A root cause finding made by the 2014/15 SAER was that the ARMD service was a "reactionary" one, with no sustainable long-term plan for the management of consumers requiring Avastin treatment. The review identified a range of factors that contributed to the unsatisfactory service at that time, and made several recommendations, including changes to systems and processes.

64. The 2014/15 SAER noted that a contributing factor was the lack of a satisfactory appointment booking system for the Eye Clinic. There was no system in place to manage the number of requests for follow-up appointments — rather, patients were put on a waiting list for an appointment and then booked into the clinic in an ad hoc manner. There were not enough appointments available, and no guidelines, clinical oversight, or audit of the administration process surrounding the booking of appointments.

65. The 2014/15 SAER recommended that:

- A service plan be developed and implemented that incorporated future demands with a long-term sustainable solution for the delivery of Avastin services.
- A workforce development plan be developed to ensure the safe delivery of patient care.
- SDHB develop clinical guidelines or a management plan in alignment with Ministry of Health work, with the aim of more standardised clinical practice.
- A process be developed that audits patients' waiting times for Avastin, to ensure that patients are being seen within the recommended timeframes.
- Patients who are overdue for Avastin be urgently re-triaged and appropriate plans put in place to ensure no further serious outcomes.
- The service provide clear guidance to its team about how to elevate clinical capacity issues.

66. The 2014/15 SAER also noted that, although not directly related to that investigation, administration team members had expressed concern about the planned appointment lists for other eye clinics, including retinal, glaucoma, general, corneal and paediatrics.

SDHB 2015/16 SAER

67. In October 2015, SDHB conducted a SAER, tabled in July 2016, in relation to Mr A's delayed follow-up for his glaucoma.[24] The event was given an SAC score of 1 — a reportable event.

[22] Treatment that successfully reverses vision loss and prevents blindness in patients with age-related macular degeneration, a condition that previously had been untreatable.
[23] A progressive disease that can lead to diminished visual acuity and loss of central vision.
[24] SAE Review number 20573 also reviewed one other patient — Review 209238. The review was conducted by a consultant ophthalmologist and a service manager.

68. The SAER's authors made the following similar findings to the previous SAER in relation to the processes involved in the treatment delay:

- Booking staff had more patients to place into clinics than there were slots available — the demand for clinic appointments exceeded the capacity.
- Other than handwritten notes on an outcome sheet, the booking staff had no indication of which patients had the greatest need to be seen.
- Booking staff received no direction as to which patients to book in a resource-constrained environment.
- The patient was not lost to the system, the patient was lost in (original emphasis) the system.
- Ophthalmology was managed primarily by a Service Manager. The Service Manager had oversight over this and multiple other services. There was only a Level 5 coordinator for the service, with responsibility primarily for nursing resource and not the overall function of the service. A separate Service Manager had overall responsibility for administration resource, but no responsibility for the Ophthalmology Service.
- Changes in clinical practice, including the introduction of new therapies and treatments, significantly increased the workload within the Eye Service. The increased workload was unable to be matched with the necessary resource, owing to the physical constraints of the department and difficulty in recruitment.

69. Dr E, as part of SDHB's responses to HDC, elaborated that the new therapies and treatments were Avastin injections. He commented:

> "[T]here has been an ongoing increase in the number of patients benefitting from these injections, however no recognition/resources/understanding (DHB or nationally) that most patients continue to need review/further injections, probably **life-long** [original emphasis]."

Conclusions of the 2015/16 SAER

70. The SAER concluded:

- The factors that contributed to the incident related to the system in place, and there was no one pivotal event or single decision that caused it to occur.
- The system was set up in a way that placed too much emphasis and responsibility upon booking staff, who did not have either the clinical oversight or sufficient information to be able to book the most appropriate patients into the clinics.
- Changes in practice in the Ophthalmology Service placed the department under pressure.
- There was a root cause of a lack of direction given to booking staff regarding high risk patients. Contributory factors included: organisation of the clinics; the methods for communicating the need for further appointments; and clinic capacity not meeting demand.

Recommendations of the 2015/16 SAER

71. The SAER made some key recommendations to SDHB:

- Review the way in which follow-up appointments are booked for patients, to include:

  i. A review of the documentation used to inform booking staff.
  ii. Ensuring that booking staff are given the appropriate direction or tools to decide which patients need to be booked in a resource-constrained environment.

- Review the number and type of each clinic that is run to ensure that patients at the highest risk of adverse outcomes by delayed appointments are able to have the shortest delays.
- Ensure that the workload of operational management staff is reviewed regularly.
- Undertake a review of the roles and responsibilities of those involved in the management of the Ophthalmology Service, to ensure that there is clarity as to where the responsibility of each part of the service resides, and therefore reducing the chance of issues "falling through the cracks".
- Clinically review the current waiting list to identify other potential patients at risk of an adverse outcome.

SDHB initiatives

72. SDHB advised that as a result of the SAER it took the following actions:

- The service adopted a risk mitigation tool. SDHB stated:

  "In response to [Mr A's] experience (in September 2015), the service adopted a risk mitigation tool, which logged each caller, assessed their acuity score at the time and responded according to an algorithm with the higher acuities seen within the week, the next band seen in the next available clinic and the lower band logged until they were able to be booked in to clinic. The risk mitigation tool is designed to assess patients' self-reporting delay. The service has always had a policy of risk being assessed by clinical staff and appropriate actions being undertaken to mitigate risk and address immediate concern."

- Additional staff were recruited. SDHB stated:

  "The approach to this problem of the Southland glaucoma service having a number of patients who were overdue for glaucoma follow-up, has been to develop a system that was sustainable in meeting patient need. To address this need, an additional part time locum ophthalmologist was employed (October 2015 onwards) and an additional full time permanent ophthalmologist with a special interest in glaucoma was recruited, starting in January 2016."

- In September 2015, the Ophthalmology Service was relocated to a larger physical environment. SDHB stated:

> "[T]he ophthalmology service was relocated to a larger physical environment to accommodate the additional staffing. This extra space made it possible to have a community optometrist see patients alongside the ophthalmologists, increasing the number of patients that can be treated in a glaucoma clinic.
>
> …
>
> Co-locating all members of the team, from being split across two floors of [Hospital 1], to one dedicated area, has improved communication making the sharing of information around at risk patients quicker and easier. Combined with the monitored telephone log addressing patients' self-reporting of risk, it is now quicker and easier for the team to respond to patient need."

- In September 2015, an acuity tool was introduced to produce a ratio for a patient's relative risk based on length of time waiting beyond that clinically acceptable. The DHB stated:

> "This has allowed the service to offer appropriate treatment to patients in order of their assessed level of acuity and need. In October 2015, the [Hospital 1] ophthalmology department redesigned its clinic schedule to ensure sufficient clinics are run each week to meet the demand and to allow extra clinics to be planned to work through remaining overdue patients."

73. SDHB also said that following identification of the problems with the Service (in September 2015), improvement work has aimed to increase the various components of the Service's knowledge of the glaucoma patients requiring care. This has given administration and clinical staff clarity of those patients most overdue for appointments, and now allows for a patient-by-patient relative assessment of need.

Further SDHB update

74. In December 2016, SDHB provided HDC with further information regarding the steps being taken.

75. In summary, SDHB advised:

- Systems have been put in place to identify the order in which patients are booked for their follow-up appointments, and to prioritise overdue ophthalmology patients. These systems include:
  i. Using a tool to develop clinically driven patient acuity scores, so that patients with higher acuities are prioritised.
  ii. Patients identified as specifically high risk must not have appointments delayed.
  iii. Patient phone call tracking logs.
  iv. Patients who self-identify with severe pain or sudden loss of vision are booked for urgent review.
- There are weekly reviews of information gleaned from the above systems.

- There are regular forums involving ophthalmology departmental staff and operational management staff.
- The roles and responsibilities of those involved in the management of the Ophthalmology Service were redefined.
- Subsequent to the October 2015 SAER, the number of overdue follow-up patients reduced from 54% of total patients to 29% as of 25 November 2016, with those waiting having lower acuities.
- An "Ophthalmology Backlog Programme" project has been established across SDHB, involving weekly stakeholder updates to track and monitor progress.
- An "Ophthalmology External Serious Adverse Events Review" was commissioned by SDHB, commencing December 2016 (and including Mr A's case).
- The Service's relocation to a larger space and increased facilities, increased patient though-put.

Ministry of Health oversight

76. The Ministry of Health is working closely with DHBs that have a backlog of ophthalmology patients, and is discussing the plans each has in place to address the issue.

77. In December 2016, the Ministry wrote to all DHBs reinforcing its support for improving capacity and managing demand. The support will include some further funding to assist DHBs to develop, implement, or improve eye health care models. (DHB service improvements may include improved capacity and demand planning, improved referral management, consistent prioritisation, and alternative workforce options.)

78. In April 2017, the Ministry of Health updated HDC on both the local DHB and nationwide actions and initiatives being implemented to address pressures being faced by a number of DHB ophthalmology services nationally.

79. In relation to SDHB, the Ministry advised that SDHB is progressing a two-phased recovery plan (tactical and strategic) to build capacity and workforce, and deliver changes to models of care respectively. SDHB provided the Ministry with its planned activity for reducing its backlog and working toward zero patients waiting beyond clinically appropriate timeframes.

80. Performance against the SDHB backlog programme project is a standing agenda item for the Ministry and DHB Executive Monitoring Intervention Framework meetings.

81. The functions of the former National Health Committee have been transitioned to the Ministry which has a work programme to identify how Health Technology Assessment (HTA) should best be carried out.

82. The Ministry advised that it has been working with the New Zealand branch of the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) to form a multidisciplinary service improvement expert advisory group.

External review of ophthalmic incidents

83. An external review commissioned by SDHB commenced in December 2016 and was completed on 24 March 2017. The review report, entitled *Review of 34 ophthalmic (eye) incidents in the Southern DHB (SDHB) identified in the period 1 July 2015 to 30 September 2016*, was made available publicly in May 2017 (see Appendix A).

84. In its analysis, key issues identified in the cases reviewed were:

- Patients were not seen in a timely manner.
- The SDHB Ophthalmology Eye Service lacked capacity to meet demand, and did not have enough appointment spaces. Capacity involves not just health professionals but also physical space, equipment, and clerical support staff.
- There was not enough recognition of the great increase in demand for eye clinic appointments to manage chronic eye disease caused by changes in the last 10 years (including the advent of Avastin treatment) occurring in the context of resourcing issues and a lack of specialists.
- Many DHBs were grappling with the issue of a rapid increase in numbers of people needing eye clinic appointments, as well as other factors such as an aging population, increasing numbers of people with diabetes, and increased rates of detection of glaucoma.

Clinically indicated time frames

85. The external review authors noted:

> "[There are] very clear recommendations for appropriate periods of review for patients with common chronic eye conditions such as diabetic eye disease, glaucoma and wet Age-related Macular Degeneration (AMD) based on large studies and extensive international experience in managing these common conditions … Numerous recent high quality clinical trials give clear timelines for appropriate review of patients undergoing treatment for wet AMD."

86. In relation to follow-up timing it was stated:

> "Appropriate patient follow-up appointment timing for the medical conditions covered by these cases, to minimise undetected major disease progression, is extremely well established. In a busy public ophthalmic (eye) service inevitably there will be some delay to follow-up with some patients. Delay of up to 1.5 times the requested review period (e.g. patient is booked for 6 months but seen at 9 months) is probably acceptable, delay stretching out to twice the requested interval is not."

Clinical prioritisation

87. The external review stated:

- The two SDHB eye service departments do not appear to have operated with a system for prioritising patients beyond a "see in (time period)" request, explaining that this becomes insufficient when the demand and volume of booked appointments required greatly exceeds the number of appointments available. Simply prioritising more patients as urgent follow-ups, effectively "grid-locked" that system in an attempt to avoid patients waiting excessive amounts of time.
- This problem of availability of appointments was "managed" by administration staff who were not qualified to, nor had clear processes for, deciding which patients should get priority, which was unacceptable.

88. The external reviewers also opined that "to some degree a culture of tolerance of unacceptable delays developed because this was the norm".

Acuity Tool

89. The external reviewers stated that while the Acuity Tool is a useful snapshot in monitoring the extent of overdue patients, it is a very limited tool in managing clinical risk. It is not a solution to prioritisation and excess demand.

90. However, strong concerns were raised that:

- The Acuity Tool initially put in place implied that wait times well in excess of the recommended evidence-based guideline time period were "low/no risk", and only waits of five times the booked time and longer were "high risk".
- Delays of more than 1.5 times the follow-up time requested carry significant clinical risk, and the Acuity Tool classifications were "quite frankly misleading" and "of serious concern" because as a rule of thumb, a patient wait of twice what has been requested is, in the reviewers' opinion, unacceptably long. It was stated that "ultimately the departments continue to lack a system to prioritise high risk patients that is effective".

91. The external reviewers stated that prioritisation schemes often use a "traffic light" classification similar to the Acuity Tool but based on clinical assessment of the individual patients — "red patients" are those who must be seen in a timely way because of the risk of serious consequences, such as loss of vision, if they are not.

DHB management on notice

92. The external reviewers outlined that:

- This was not a newly arising problem, but rather a culmination of insufficient responses by senior management to growing demands for ophthalmology services over a number of years — an issue flagged by the ophthalmic workforce, including evidence that the problems in Southland were raised on a number of occasions, having sighted examples from a long series of documents viewed.

- Staff from the ophthalmic (eye) services did attempt to communicate their concerns regarding the growing problem to management but "the scale of the response needed was not realised, and management did not appear to understand that the concern was that patients were losing vision because they were not getting treatment within evidence based timeframes".

Other issues

93. The external reviewers also made the following points:

- In cases where patients lost to follow-up called the Ophthalmic Service, generally telephone calls received by Hospital 1 were not handled by clinical staff, and were not followed up with reference to the clinical record. For a period, calls were not necessarily recorded, and, if recorded, this was not systematic. Calls were not referred to clinical staff, and did not result in action. Patients under the care of the Eye Service need to have unobstructed telephone access to clinical staff.
- A barrier to adequate resourcing is the relatively limited understanding by senior management and by medical colleagues from other specialties as to what ophthalmologists actually do. Ophthalmology was seen as a surgical specialty when it is predominantly a medical specialty, with a majority of time being spent in clinic treating patients with chronic conditions, and rarely involving theatre.
- There are no Elective Services Patient Flow Indicators (ESPIs) relating to reviewing patients with chronic disease in a timely manner, meaning that in order to meet ESPIs relating to new referrals and patients booked for surgery, new patients were prioritised over follow-ups, and surgical lists over outpatient clinics.
- Delays in patients having ophthalmic medical consultations is not a newly arising problem, but is rather the culmination of insufficient responses by senior DHB management to growing demands for ophthalmology services over many years.
- The problem of capacity in Southland was compounded by long-standing issues recruiting and retaining ophthalmologists.
- Demands, and efficient clinics, cannot be met by specialist-only services. Ancillary clinicians (such as optometrists, trained nurses, and technicians) also need to be used.
- It is essential that the service have in place a robust auditable process for tracking and accounting for all referrals.
- An underlying cause of the communications and efficiency problems identified has been the deficiencies in governance of the two SDHB ophthalmology departments.
- External review of the Hospital 1 Eye Service systems and process was suggested, along with formal credentialling of the two SDHB ophthalmology departments.

94. The external review made nine detailed recommendations[25] covering issues of capacity, management of the departments, prioritisation, telephone systems, management of referrals and follow-up, efficiency, credentialling, national improvements, and shared learning.

Further updates to HDC

95. In May 2017, SDHB confirmed that all the recommendations arising out of its October 2015/16 SAER had been completed by the end of September 2016.

96. SDHB also stated:

> "The current state of the outpatient waiting list is assessed weekly, looking at patient number trends by the quality performance and systems manager and forwarded to the area management who feedback to the clinical team at their bi-weekly meeting.
>
> The complete planned waiting list is examined weekly by the service to identify patients' expected wait times and allow the allocation of resources. This is undertaken using the acuity tool model which identifies the current time waiting as a ratio against the expected clinically decided wait time. This in conjunction with patients identified as 'do not delay' allow a view of those patients that have greatest need to use the services available."

SDHB's response to external review

97. In June 2017, SDHB provided HDC with its action formulated to address the issues, concerns, and recommendations arising from the external review. The action plan has been designed and reviewed by an ophthalmology project team and an ophthalmology steering group. These teams both include a mix of senior management and clinical staff.

Prioritisation system

98. SDHB told HDC that:

- It has specifically addressed the external review author's conclusion that "ultimately the departments continue to lack a system to prioritise high risk patients that is effective".
- The Ophthalmology Clinical Leader undertook discussions with the external report's medical reviewer and SDHB ophthalmology consultants to implement a three-level prioritisation or "traffic light" system.
- The system will add value to the information available to the booking staff, and enable them to identify high-risk patients better. The "do not delay" category is one of these and will be used uniformly to signify that a patient's appointment must not be booked past the requested date. "Do not delay" patients are identified

[25] See page 26 of the external review.

by clinical staff at the time of appointment, to ensure that those who are the highest risk are booked in to the soonest available appointment to their due date.

Responses to provisional opinion

99. Mr A had no additional comments to make in relation to the "information gathered" section of the provisional opinion.

100. SDHB had no further comment, other than to indicate that it remained sincerely regretful that Mr A suffered a loss of sight as a result of the delay in treatment he experienced.

Opinion: introduction

101. As detailed in the external review, a combination of factors has driven rapidly increasing demand for ophthalmology services in New Zealand, including outpatient clinic time, over the last 10 years. A key factor has been the introduction of very effective new therapies and treatment (such as Avastin), which has resulted in consumers needing to see specialists for regular ongoing follow-up and/or treatment, fuelling increased demand for ophthalmology services. I consider that the Ministry of Health has a role, with DHBs, to recognise the effect of the introduction of such new technologies and associated pressures on the system, and plan accordingly.

102. Provider accountability is not removed by the existence of systemic pressures. A key improvement that all DHBs and the Ministry of Health must make, now and in the future, is to assess, plan, adapt, and respond effectively to the foreseeable effects that new technologies will have on systems and demand.

Opinion: Southern District Health Board — breach

Introduction

103. The facts of Mr A's case are not in dispute. Put simply, Mr A did not receive follow-up ophthalmology specialist care relating to his glaucoma management in line with the clinical time frames requested by his clinicians.

104. Mr A should have had a follow-up appointment in approximately March 2015, but this was delayed by six months.

105. By the time of his 9 September 2015 appointment, Mr A had suffered vision loss in his right eye (which I note many clinicians subsequently attributed to the delay) and he required an urgent referral to Hospital 2 for management and surgery.

106. When it became apparent to Mr A's clinicians that the instructions for follow-up appointment scheduling had not been carried out, they advocated for Mr A and facilitated necessary action.

107. As I have emphasised in previous cases, district health boards (DHBs) are responsible for the operation of the clinical services they provide, and are responsible for any service failures.[26]

108. It is incumbent on all DHBs to support their staff with systems that guide good decision-making and promote a culture of safety.[27] In addition, it is the responsibility of DHBs to prioritise patients appropriately and in a timely manner, and provide patients with good information, particularly when waiting for resource-constrained specialist services.

Demands on the Ophthalmology Service and management response

109. I am fully cognisant of the complex resourcing pressures and associated demographic factors at play affecting long-term ophthalmology treatment in New Zealand, including the prevalence and incidence of chronic eye disease and its resulting demands on the system. This issue is described in helpful detail by the external reviewers' analysis.

110. I am also mindful of the more recent reviews and subsequent actions taken by SDHB to address the deficiencies identified.

111. At the time of Mr A's care, the Ophthalmology Service at SDHB lacked capacity, in that the clinics did not have enough appointments for the number of patients clinicians had to see.

112. This was contributed to by an insufficient response by senior management at SDHB to growing demands for ophthalmology services over many years. Clinical staff attempted to communicate to management the concerns regarding the growing problem. However, there was a lack of recognition among management at SDHB of the clinical risk caused by this lack of capacity — that patients were losing vision because they were not being seen within evidence-based timeframes. In addition, I note the reviewers' comment: "[W]hen efforts to increase funding, staff and capacity have been declined, there does not appear to have been any assessment of the risk consequent from such decisions, and the opportunity to identify the problem, and that it was being compounded, was missed at these decision points."

113. In the context of resource constraint, prioritisation schemes become vital in ensuring that those patients at greatest risk are seen first. However, as is detailed below, SDHB's Ophthalmology Service lacked an appropriate prioritisation system.

114. SDHB management failed to communicate effectively with its clinical staff and act on valid concerns raised by senior clinicians, and to ensure that a system was in place

[26] See also Opinion 14HDC01187 (30 June 2016).
[27] Opinion 09HDC02089 (4 July 2012).

that effectively managed and appropriately prioritised patients waiting for follow-up specialist ophthalmology care, including those at higher risk. I am also concerned at the comment by the reviewers that "to some degree a culture of tolerance of unacceptable delays developed because this was the norm". In this environment, delays became normalised and, as a result, SDHB tolerated a situation that put patients at risk. Even when a system is under pressure, appropriate patient prioritisation must be the central focus.

115. These are issues of central importance for all DHBs that, if not recognised and acted on, can have severe consequences for consumers. In this case, SDHB's inaction failed Mr A.

Lack of a prioritisation system

116. At the time of Mr A's care, SDHB told HDC that its process was for Hospital 1 administration staff to book and prioritise follow-up review appointments requested by the clinician. These staff did not have the clinical oversight necessary to be able to book the most appropriate patients into clinics. SDHB acknowledged that the lack of capacity in the service placed the service in crisis and, without hands-on day-to-day management, allowed the administration staff to make decisions for which they were not qualified. Additionally, the system of prioritising patients based entirely on clinicians' initial requests became inadequate when demand exceeded capacity.

117. On 16 September 2014, at Mr A's appointment with Dr E at Hospital 1, Dr E requested a follow-up interval of six months. Dr E hand wrote in his notes: "R/v [six months] (sooner if problems)."

118. The requirement for a follow-up appointment for Mr A in six months' time was entered into the SDHB iPM electronic patient management system appropriately. The external review noted that appropriate patient follow-up appointment timing for the medical conditions covered by these cases, to minimise undetected major disease progression, is extremely well established. The external review acknowledged that in a busy public ophthalmology service, inevitably there will be some delay in follow-up for some patients. However, the reviewers stated that delay stretching out to twice the requested interval is not acceptable.

119. Mr A's follow-up appointment did not occur within the six-month timeframe specified by Dr E. Clearly this was suboptimal.

120. In October 2015, SDHB conducted a Serious Adverse Event Review (SAER) in relation to Mr A's delayed follow-up (tabled in July 2016). As well as confirming that Mr A was lost in the system, the SAER found:

- The system was set up in a way that placed too much emphasis and responsibility upon booking staff, who did not have either the clinical oversight or sufficient information to be able to book the most appropriate patients into the clinics.
- Booking staff had more patients to place into clinics than there were slots available — demand exceeded the capacity.

- Booking staff had no indication of which patients had the greatest need to be seen, other than handwritten notes on an outcome sheet.
- Booking staff received no direction as to which patients to book in a resource-constrained environment.

121. I am concerned that issues regarding the booking system had already been raised in the previous SAER completed in January 2015 (which I acknowledge focused more closely on Avastin treatment). That SAER noted that there were not enough appointments available, and no guidelines, clinical oversight, or audit of the administration process surrounding the booking of appointments. The 2014/15 SAER also noted that although not directly related to that SAER, administration team members had expressed concern about the planned appointment lists for other eye clinics, including retinal, glaucoma, general, corneal, and paediatrics. It is evident, then, that SDHB was on notice that its booking staff were concerned about the effect of heavy demand on other arms of the Eye Service, and that a satisfactory booking system was lacking. I am critical that SDHB had not acted effectively on those concerns by the time of the 2015/16 SAER.

122. SDHB told HDC that the Service Manager for the Surgical Directorate responsible for ophthalmology understood it to be the administration staff's responsibility to book the patients in to clinic, and believed that follow-up patients were booked for clinic visits as close to their planned date as possible. SDHB advised that while booking concerns and issues were broadly discussed fortnightly with the Surgical Services Manager and clinical team, including the booking staff, operational day-to-day decision-making for booking criteria was not part of this discussion.

123. Prioritisation of booking of appointments was managed by administration staff, who were not qualified to decide which patient should get priority, nor did they have clear processes to assist them to do so. I consider this situation to have been unacceptable, and I note that the external reviewers also came to this conclusion.

124. At the time of Mr A's care, the only criteria considered when booking appointments was the time period requested by the clinician, rather than the particular patient's risk factors.

125. Essentially, this approach was flawed when the volume of booked appointments required greatly exceeded the number of appointments available. Simply prioritising more patients as urgent, not surprisingly, grid-locked such a system. I consider that the lack of an appropriate prioritisation system at SDHB that focused on patients' clinical need, including specific risk factors, contributed to the delay in Mr A's follow-up appointment. In a resource-constrained environment, a proper prioritisation system ensures that those with risk of serious consequences are seen in a timely manner.

126. It is also concerning that SDHB told HDC that it could not locate any evidence of records of training, orientation, or induction material for its Eye Service administration staff, nor could it explain to HDC in any detail how it had assisted its staff in the effective management of follow-up appointments, or what role, if any, its "Administrative Procedure Manual" played.

127. In my view, it was wholly inappropriate for SDHB booking staff to be tasked with the important responsibility of prioritising ophthalmology follow-up appointments without supporting those staff with sufficient training, clinical oversight and input, sufficient information on which to base prioritisation decisions, and clear direction about what might constitute a higher risk patient requiring clinical escalation. In this respect, SDHB failed its staff as well as consumers, including Mr A.

128. I also consider that there were missed opportunities for SDHB to remedy the delay in scheduling Mr A's follow-up appointment. For instance, Mr A rang to follow up his appointment on several occasions from around April–May 2015 (seven to eight months after his appointment), and in August 2015 he reported changes in the symptoms that he was experiencing. Also, on 4 August 2015 Dr E made a handwritten comment on a letter received by SDHB from Mr A's GP that Mr A's follow-up was delayed, and Dr E requested urgent review in two months' time or less. That note was not actioned.

129. Mr A told HDC that in August 2015 he rang the Eye Clinic and demanded an appointment. He told hospital Eye Clinic staff that if they did not give him an appointment he would go to the hospital and not leave until he was seen.

130. However, generally such calls were not handled by clinical staff and were not followed up with reference to the clinical record. For a period, calls were not necessarily recorded. The reviewers were of the view that "patients under the care of the eye service need to be able to have unobstructed phone access to clinical staff".

131. An effective consumer-centred system must be able to respond to clinical concerns raised by patients, document these, and have an escalation pathway in place that staff can follow where clinically indicated. I am concerned that at the time of Mr A's care, Hospital 1 Eye Clinic staff kept no records of the telephone calls it received from patients, including patients reporting concerning clinical symptoms, and there was no system to escalate such calls to clinical staff.

Conclusion

132. In situations such as this, it is crucial that leadership is integrated and, in my view, accountability lies across clinical and senior management.

133. SDHB failed to arrange a timely follow-up appointment for Mr A because SDHB did not have a prioritisation system that focused on patients' clinical need, and instead relied on administration staff, who lacked training and clear guidance to prioritise appropriately. Despite concerns being raised with SDHB, SDHB did not recognise the clinical risk created by the lack of capacity at the Ophthalmology Service, and did not take action to rectify the situation after the 2014/15 SAER. In addition, there were missed opportunities for SDHB to rectify the delay in Mr A's follow-up appointment. In my view, SDHB did not provide services to Mr A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Recommendations

134. I recommend that within three months of this report, Southern District Health Board provide HDC with a detailed update report on the steps taken to carry out both the external reviewers' recommendations and those arising out of SDHB's own reviews, with specific reference to:

a) An independent evaluation of the systems in place to identify and prioritise overdue ophthalmology patients. This should include the use of clinically driven patient acuity scores so that patients with higher acuities are prioritised and patients identified as specifically high risk do not have appointments delayed, and patients who self-identify with severe pain or sudden loss of vision are booked for urgent review.

b) A quantitative and qualitative audit of the management of Ophthalmology Service referrals and follow-ups since December 2016, to be certain that tracking systems are in place so that all referrals are responded to in a timely manner.

c) The proactive steps taken to build departmental capacity, responsiveness, and adaptability, including regular accurate measurement and reporting of demand and capacity, using objective agreed criteria that account for actual and projected increases in demand, as well as details regarding:
   - Training and implementation of nursing staff and ancillary and non-specialist staff to remove inefficiency associated with lower priority tasks.
   - The effectiveness of the department's relocation to enhanced physical space.
   - Recruitment of ophthalmologists, optometrists, orthoptists, and ophthalmology staff.

d) Details of the redefined roles and responsibilities of those involved in the management of the Ophthalmology Service.

e) Routine telephone access to clinical staff so that DHB Eye Service patients, across both centres, can contact the Eye Department readily, speak to an appropriately trained person when clinical concerns are raised, receive an appropriate response, and have this recorded in their clinical notes.

f) Shared learning:
   - Use of regular forums involving ophthalmology departmental staff and management staff, to include discussion and planning to assist development of treatment protocols in the context of an ageing population.
   - Confirmation that the external review report was discussed with all other DHBs via their Chief Medical Officers, to ensure that any patient risk arising from similar circumstances is identified and controlled.

g) The Ophthalmology Service and its facilities undergoing regular credentialling, as occurs in most DHBs.

h) A further update on how the Ophthalmology Backlog Programme project has been established across SDHB, involving its weekly stakeholder updates to track and monitor progress toward zero patients waiting beyond clinically appropriate timeframes.

135. I also recommend that Southern District Health Board provide a formal written apology to Mr A. The apology is to be sent to HDC for forwarding, within three weeks of the date of this report.

136. I endorse the recommendation made by the external review (8(c)) and recommend that the Ministry of Health establish systems to identify worthwhile major new healthcare technologies, such as the advent of Avastin therapy, in the future, so that adequate planning and funding responses can occur in a timely way, and report to me on progress towards the development of those systems (including HTA), within six months of the date of this report.

137. I recommend that the Ministry of Health update me on the progress it has made towards addressing the other national improvement recommendations made by the external review, including a national discussion on ophthalmology priorities (such as that initiated with RANZCO), and national reporting of overdue eye appointment statistics, within one month of the date of this report.

Follow-up actions

138. Southern DHB will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994, for the purpose of deciding whether any proceedings should be taken.

139. A copy of this report with details identifying the parties removed, except Southern District Health Board and the Ministry of Health, will be sent to HQSC, the Royal Australian and New Zealand College of Ophthalmologists, the National CMO Group, and Central Technical Advisory Service (TAS), and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

140. The Director of Proceedings decided not to issue proceedings.

Appendix A: External review report

Southern District Health Board commissioned the following external review, entitled *Review of 34 ophthalmic (eye) incidents in the Southern DHB (SDHB) identified in the period 1 July 2015 to 30 September 2016*, by Dr James Stewart, ophthalmologist, and Kate MacIntyre, consultant, dated 24 March 2017, and available publicly from May 2017:

"**Review Process**

Dr Jim Stewart (Ophthalmologist, Counties Manukau District Health Board) and Kate MacIntyre (Independent Consultant, Kate MacIntyre Consulting Ltd.) were asked by Southern DHB (SDHB) to complete a review of 34 ophthalmic (eye) cases that SDHB had identified in the period 1 July 2015 to 30 September 2016.

SDHB staff completed incident reports, and these were then each assessed as meeting the criteria of a Serious Adverse Event (SAE). An *Incident* is defined as any event that *could have* or *has caused* harm and an *Adverse Event* is an Incident that *has caused* harm. A SAE is an adverse event that when scored according to the New Zealand Health Quality and Safety Commission's (HQSC) Reportable Events Policy and Severity Assessment Criteria tables is recorded as Severity Assessment Code (SAC) 1 or 2 i.e. Severe, Major or Moderate harm events.[1,2]

SDHB initiated and completed their own internal review processes for these SAE's. However due to the multiple number of events SDHB also requested this independent review. The reviewers were asked to provide a report giving an overview of what was learnt through root cause analysis of the problems that led to the events. In particular the reviewers were asked to identify any factors which contributed to the incidents, review interventions introduced to address the problems, and identify any further opportunities for improvement.

The review process included:

1. Review of the patients' clinical records.
2. Review of SHDB internal review reports.
3. Review of relevant SDHB reports, documents and data.
4. Interview of relevant SDHB staff.
5. Site visit to Dunedin Hospital ophthalmic (eye) service.
6. Development of a draft report.
7. Provision of the draft report to staff interviewed for factual correction.
8. Provision of the final draft report to Dr Nigel Millar, Chief Medical Officer SDHB for comment.
9. Provision of a final report to SDHB.

[1] http://www.hqsc.govt.nz/assets/Reportable-Events/Publications/Reportable-Events-Policy-Final-Jan-2013.pdf
[2] http://www.hqsc.govt.nz/assets/Reportable-Events/Resources/SAC-Matrix-1-July-2013.pdf

The reviewers did not interview any patients. The reviewers acknowledge that each 'case' is a patient who has suffered and worried. Vision loss is devastating, delayed treatment for malignancy is distressing, and development of vision threatening disease is worrying. The reviewers extend their condolences to all patients and their family/whanau.

The reviewers would like to acknowledge and thank all the staff they met with for their professional and helpful responses. The reviewers appreciate that staff have been under considerable stress since this situation became apparent.

Executive Summary

Dr Jim Stewart (Ophthalmologist, Counties Manukau District Health Board) and Kate MacIntyre (Independent Consultant, Kate MacIntyre Consulting Ltd.) were asked by Southern DHB (SDHB) to complete a review of 34 ophthalmic (eye) cases that SDHB had identified in the period 1 July 2015 to 30 September 2016. Given the number of cases, the reviewers did not interview any patients. The reviewers acknowledge that each 'case' is a patient who has suffered and worried. Vision loss is devastating, delayed treatment for malignancy is distressing, and development of vision threatening disease is worrying. The reviewers extend their condolences to all patients and their family/whanau.

The reviewers would like to acknowledge and thank all the staff they met with for their professional and helpful responses. The reviewers appreciate that staff have been under considerable stress since this situation became apparent.

In all but one of the cases, the issue is entirely that the patient was not seen in a timely manner. Whilst other factors are involved, the over-riding reason why patients were not seen when they should have been was because the two eye departments lacked capacity to meet the demand for their services: the clinics did not have enough appointments for the patients they had to see.

The SDHB ophthalmic (eye) service lacked capacity, we believe, because there was not recognition of the great increase in demand for eye clinic appointments to manage chronic eye disease caused by the changes of the last ten years: primarily (but not only) the advent of Avastin treatment for wet macular degeneration (AMD), a condition which had been previously untreatable, and hence not generating need for clinic appointments. This occurred in the context of previous under-resourcing, and gaps in ophthalmologist supply in both Invercargill and Dunedin. We also note the wider context of significant financial constraints for the SDHB in recent years.

In all the cases the issue was that it appeared that harm had come to the patient because of delay in the patient being seen. In most cases patients with chronic disease were not seen for follow-up within the time period requested by the clinician who had seen them at an outpatient consultation. In two cases delay occurred because referrals to the service were lost. One case is complex with a number of factors including delay involved. We did not agree, on the

information we had available, and with the passage of time, that eleven of the thirty four cases were in fact SAEs. A number of cases developed vision threatening disease without losing significant vision. However fourteen patients suffered moderate or major loss of vision directly attributable to delay, and two additional cases involved significant delay in managing malignant disease, with risk to patient life. Many patients were lost to follow up.

We note that since 2015 the DHB has made considerable effort and taken many very worthwhile actions to address the issues raised in this review, but we consider that there is more that needs to be done.

We recommend that SDHB Ophthalmology services capacity be increased: clinical staff, support staff, equipment and physical clinic space. Governance of the two departments is inadequate: we recommend that each department have a dedicated manager or coordinator. A clinical prioritisation system should be implemented, patient phone access be addressed, referrals and follow-ups be tracked and audited, there needs to be ongoing review of clinic efficiencies, and departmental credentialing should be performed. We further recommend national establishment of priorities for ophthalmic services, systems to forecast and react to new technologies, and the sharing of the learning from this report with other DHBs to ensure any patient risk arising from similar circumstances is identified and controlled. We consider this will require all DHBs to have systems monitoring overdue appointments for patients with chronic potentially vision-threatening eye conditions, and that there may be a role for national implementation of the Acuity Tool to monitor the extent of the overdue follow-up problem.

Chronology

The following provides a brief summary overview of key relevant events related to the SAEs under review. Given the number of SAEs considered in this review it has not been possible to provide detailed timelines for each case.

When did the errors leading to the SAEs we are studying occur?

We are aware that whilst we are looking at SAEs reported from June 1st 2015 to Sept 30th 2016, the error leading to the SAEs often occurred in an earlier period. If we work on the basis that error occurred when a patient was not seen as booked, our SAEs occurred as follows:

2011 1 case

2013 1 case

2014 3 cases

2015 6 cases in first 6 months and 6 cases in the second 6 months

2016 6 cases in first 6 months

(1 case not known)

Timeline

In the period to May 2010 the two ophthalmic (eye) services operated under different District Health Boards (DHBs) — Dunedin was under Otago DHB and Invercargill was under Southland DHB. Following the creation of the Southern DHB, the services continued to operate under separate Group/Directorate managers until January 2013 when a District-wide Directorate structure was put in place.

7/12/2009	Email from Senior Medical Officer (SMO) 1 to the Unit Manager Eyes/ENT/Rheumatology raising concerns about the number of patients who had not received follow up appointments.
Jan 2010	SMO 2 began working in Dunedin.
30/4/2010	Dunedin Eye Department Senior Staff Meeting (SSM) minutes record that a box of unprocessed follow-ups dating back to 2006 had been found in a cupboard. (SSM from here forwards refers to the Dunedin Eye Department Senior Staff Meeting)
27/8/2010	SSM minutes record that all patients lost to follow-up now have appointments.
5/11/2010	SSM minutes record that the problem of clinic capacity discussed, including concern that a potential 'cupboard' being created again.
25/2/2011	SSM minutes record that semi urgent patients 'as of now' were being sent back due to the 'number of follow ups who are being lost' due to clinics not being available.
25/3/2011	SSM minutes record ongoing concern with patients lost to follow-ups due to too many new patients and not enough clinic slots. Issue to be discussed with Chief Operating Officer. Action; new patients only seen if urgent.
2011	SMOs initiate a meeting with Planning and Funding and other members of the surgical directorate (Service Manager and Chief Operating Officer attended) re concerns about overdue follow ups.
July 2011	SMO 3 commenced at Invercargill — 0.5FTE
Nov 2011	SMO 4 commenced at Invercargill

3/2/2012	SSM minutes record that the Dunedin Unit Manager was to bring planned reports about pressure on clinic appointments to P&F (Planning and Funding).
5/6/2012	Email from CEO, to immediate sub-ordinates supporting concerns raised about the ophthalmology service following a meeting between her and SMO 5 (Clinical Leader) and SMO 2 (about to take over as Clinical Leader) the week before.
June 2012	SMO 2 assumed the role of Clinical Leader for the ophthalmology (eye) service at the Dunedin site, and across the District the following year.
25/1/2013	SSM minutes record problems, due to volumes in booking follow-up appointments. SMO 2 proposed 50% protocol — allows appointment to be booked up to 50% of the original requested time e.g. a 6 month follow-up could be booked at 9 months. Noted in many instances already beyond this timeframe.
Oct 2013	Report on blow-out in follow-up numbers by SMO 2, to Specialist Surgical Services Manager, Dunedin Public Hospital. Clinician concerns regarding patient risk and medico legal risks for the DHB noted.
8/11/2013	SSM minutes record that SMO 2 provided a plan for follow-up of patients not seen due to volumes.
6/11/2013	Email from visiting ophthalmologist SMO 6 sent to General Manager, Surgical Directorate, raising alarm about inability of the Invercargill ophthalmic (eye) department to meet demand. Noting 'We are way behind in Avastin injections, and have a system of glaucoma assessments that is unable to keep up with demand', '… we are getting far behind in crucial areas such as diabetic screening and glaucoma … our nurses are struggling to keep pace with the demands on them'.
Nov 2013	Email from SMO 2, to Eye Department doctors and nurses at Dunedin and Invercargill proposing a planning day to 'try to tackle … our overdue follow-up problems'.
Jun 13–Nov 13	Protected Quality Assurance Activity[3] (PQAA) report recorded 'Significant problems and issues: Current concerns relate to the

[3] NB. This information is provided as another example of how concerns were reported and raised and only includes information which was already being reported via other mechanisms, i.e. was known and was not information that came to light solely as a result of the departments PQAA audit activity. As such we consider it reasonable to include this information.

	number of patients … waiting longer for their follow-up appointments than intended.'
Feb 2014	Ophthalmology Planning Day held.
Dec 13–Jun 14	PQAA report recorded — Significant problems and issues: Continuing work being done regarding patients who are overdue for follow-up.
April 2014	The Medical Director discussed the Southland issues with the Clinical Leader for ophthalmology and requested a visit to the Southland site.
Jul–Sep 2014	5 incidents of vision loss due to delay in seeing Avastin patients reported in Invercargill.
9/9/2014	Letter from SMO 2, to General Manager, Surgical Directorate outlining serious concerns of the Senior Medical Officers in the Dunedin Eye Department re patients overdue for follow ups.
26/9/2014	Letter from SMO 2, to CEO, thanking her for coming to hear about the overdue follow up issue, and trusting that the CEO will be able to present the needs of the district to the Ministry to improve the care that can be provided.
Oct 2014	Investigation into 5 SAEs in Southland begun, none of these are included in the cases we are looking at. Quality role incumbent resigned and replaced with seconded staff member.
Jun 14–Nov 14	PQAA report recorded concerns regarding visual outcomes for glaucoma patients overdue for follow-up in Dunedin and concerns regarding delayed follow-up of patients after Avastin injections in Invercargill.
7/1/2015	Invercargill SAE Report into 5 SAC 2 incidents of vision loss from delayed Avastin injections which occurred from July to Sept 2014. The report described an out of control clinic booking system where patients were essentially loaded onto a wait list, 'always more patients than slots', no guidance to clerical staff as to priority, no clinical oversight of the process, no mechanism for staff to alert management that the system was under stress (although staff had tried to do this), no auditing, staff working in a toxic workplace dealing with angry and upset patients.

'The root cause … is that the ARMD (age related macular degeneration) service is a reactionary service with no sustainable long term plan for the management of Avastin patients. There are a range of contributing factors including:

- Lack of satisfactory appointment booking system
- Lack of knowledge re demand both current and future
- Lack of demand versus capacity matching in terms of clinics and resources
- Lack of clear clinical pathway for patients
- Lack of medium to long term service plan
- Elevation of capacity versus demand issues did not result in long term solutions for the service'

Recommendations included:

- A service plan is developed and implemented that incorporates the current and predicated future demands with a long term sustainable solution for the delivery of Avastin services across the district.
- Develop and implement a workforce development plan to ensure the safe delivery of patient care, this may include a variety of providers including GP's, Clinical Nurse Specialists, SMO's, other health professionals, clinical support and administration staff.
- SDHB develops clinical guidelines/pathway or a management plan in alignment with Ministry of Health work, with the aim of more standardised clinical practice when clinically appropriate. This will be essential to inform the service planning and workforce development plans.
- The patient booking system is changed so that patients receive the next appointment prior to leaving the department (already implemented).
- There is a process developed that audits patients waiting times for Avastin, to ensure that patients are being seen within the recommended timeframes.
- Patients who are currently overdue for Avastin are urgently re-triaged and appropriate plans put in place to ensure that there will be no further serious outcomes.
- The service provides clear guidance to its team regarding how to elevate clinical capacity issues, and then for the service to demonstrate how it will feedback to the team regarding action taken in response.

March 2015 — Quality Performance and Systems Manager newly appointed for the Surgical Directorate begins a thorough review of processes both in Dunedin and Invercargill.

	Electronic incident reporting system (Safety1st) implemented.
Dec 14–May 15	PQAA report recorded concerns regarding the number of patients who have delayed follow-up.
April 2015	SMO 2 inspects and reports on Invercargill department noting issues of staff stress, patients with delayed follow-up, lack of space, and inefficiencies such as low clinic numbers.
8/4/2015	SMO 4 — in reply to request for agenda items for Senior Medical Staff Committee Southland Hospital — requests agenda and minuting of concerns: the eye department workload of follow up patients, the CNS on sick leave 'from burnout', staff doing significant overtime and extra clinics. Concerns have been raised with management over the last two years. While there is an effort to create a business plan to increase staff and space this will take time and 'we don't know how to cope with our current situation'.
8/4/2015	SMO 4 emails Southland Senior Medical Officer and General Manager Surgical Directorate raising concerns regarding staff burnout and that 'while the Avastin "problem" has improved currently, time has been taken away from other clinics causing delays and possible sight threatening problems'.
14/5/2015	SMO 7, Chair and on behalf of the Senior Medical Staff Committee Southland Hospital writes to Clinical Leader Ophthalmology and Medical Director Surgical Services SDHB noting discussion of concern regarding Ophthalmology at Invercargill, belief that the service is 'very stretched' and noting concerns from other services.
June 2015	Beginning of period in which the incidents we are looking at were reported. (Our best determination as to when the error actually occurred reported above).
July 2015	SMO 8 commenced as a locum at Invercargill
Sept 2015	The Acuity System, a systematic process to prioritise those most at risk of irreversible sight loss implemented in Southland. Southland moved into new clinic, much more space, able to use optometrists. Staff now all co-located rather than scattered around the building. Case I1 re-presented, SAE investigation begun Oct 2015.

25/9/2015	Combined SDHB Ophthalmologists write letter to General Manager Surgical Directorate, raising further concerns about under resourcing and their ability to maintain appropriate follow-up, and clinical care and prevent blindness.
Oct 2015	Briefing Paper for Provider Arm Executive re Overdue Outpatient Follow-ups in Southland. Recommending urgent implementation of short term plans, fast tracking of medium term plans, additional short term risk management actions and commencing medium–long term actions, and urgent review of the situation in Dunedin.
Jun 15–Nov15	PQAA report recorded concerns continuing regarding the number of patients who have delayed follow-up.
Jan 2016	New FT ophthalmologist in Southland
July 2016	SMO 8 employed permanently at Invercargill — 0.5FTE
July 2016	Reports re 2 SAE tabled I1 & I4

SAE Review 20573 & 20928 — Findings:

1. Booking staff had more patients to place into clinics than there were slots available — the demand for clinic appointments exceeded the capacity
2. Other than handwritten notes on the outcome sheet the booking staff had no indication which patients had the greatest need to be seen
3. Booking staff received no direction as which patients to book in a resource constrained environment
4. The patients were not lost to the system, they were lost in the system
5. Similar clinical outcomes could have occurred to innumerable patients
6. Change in clinical practice including the introduction of new therapies and treatments significantly increased the workload within the eye department. This increased workload was unable to be matched with the necessary resource due to the physical constraints of the department and difficulty in recruitment
7. Ophthalmology is managed primarily by a Service Manager. The Service Manager has oversight over this and multiple other services. There is only a Level 5 coordinator for this service with responsibility primarily for nursing resource and not the overall function of the service. A separate Service Manager has overall responsibility for administration resource but no responsibility for the ophthalmology service.

Root Cause: Lack of direction to the booking staff regarding high risk patients.

Contributory Factors:

1. Organisation of the clinics.
2. The methods for communicating the need for further appointments.
3. Clinic capacity not meeting the demand.

Recommendations:

1. Review the way in which follow-up appointments are booked for patients to include:
   a) Review of the documentation used to inform booking staff.
   b) Ensure booking staff are given the appropriate direction or tools to decide which patients need to be booked in a resource constrained environment.
2. Review the number and type of each clinic that is run to ensure that the group of patients at the highest risk of adverse outcomes by delayed appointments are able to have the shortest delays.
3. Ensure that the workload of operational management staff is regularly reviewed especially when dealing with a service with known issues.
4. Undertake a review of the roles and responsibilities of those involved in the management of the ophthalmology service. This is to ensure that there is clarity as to where the responsibility of each part of the service resides and therefore reduces the chance of issues 'falling through the cracks'.
5. Clinically review the current waiting list to identify other potential patients at risk of an adverse outcome.

SDHB Initiatives

It needs to be recognised that since 2015 the DHB has made considerable effort and taken many very worthwhile actions to address the issues raised in this review. These include:

— Relocating the Invercargill ophthalmic (eye) department into expanded facilities.

— Employing two new ophthalmologists in Invercargill.

— Instituting the Acuity System to monitor the extent of the overdue follow-up problem in Invercargill then Dunedin.

— Ensuring patients with 'greatest acuity' (longest extra wait) are seen, triaging notes of patients with high acuity.

— Regularly monitoring progress to address the issues including regular reporting to the Provider Arm Leadership Team.

— Running an effective Quality System, facilitating easy reporting of incidents, and following up on investigating these.

— Directing Quality staff to look in to the services, in particular seconding the surgical Directorate Quality & Performance Improvement Facilitator.

— Running extra clinics in Invercargill and Dunedin.

— Efforts to ensure patients with less serious problems are not seen or are discharged from clinics.

— Hiring more nurses and ancillary ophthalmic clinical staff, e.g. optometrists.

— Efficiencies in clinical processes in Invercargill.

— Looking at models of care in both centres, including a system wide model of care for glaucoma.

We still however feel that there is more that needs to be done, for instance, 18 of our 23 cases occurred (as defined above) during 2015 and 2016, generally after the above initiatives had been commenced. Obviously, also, it will take time for many of these actions to have their full beneficial effects.

Findings

We have been asked to look at the root causes for 34 cases where it was felt that eye patients had come to harm in the SDHB over a fifteen month period. We note that the SAEs identified will be the tip of the iceberg, e.g. glaucoma progression over recent years as a result of extended waiting times between clinic visits may lead to blindness in future. All cases reported can be considered 'accidents waiting to happen' and similar incidents are very likely to continue to occur in the next 1–2 years unless significant measures are undertaken to alter the situation for ophthalmic care in the DHB.

In all but one of the cases we were asked to review, the issue is entirely that the patient was not seen in a timely manner. Whilst other factors are involved, the over-riding reason why patients were not seen when they should have been was because the two eye departments lacked capacity to meet the demand for their services: the clinics did not have enough appointments for the patients they had to see. Capacity refers not just to health professionals, in our context specialist ophthalmologists, other doctors, nurses, optometrists and orthoptists; but also to physical space, especially clinic rooms, to equipment, and to clerical support staff.

The SDHB ophthalmic (eye) service lacked capacity, we believe, because there was not recognition of the great increase in demand for eye clinic appointments to manage chronic eye disease caused by the changes of the last ten years.

Primarily (but not only) the advent of Avastin treatment for wet macular degeneration (AMD), a condition which had been previously untreatable, and hence not generating need for clinic appointments. This occurred in the context of previous under-resourcing, and gaps in ophthalmologist supply in both Invercargill and Dunedin. We also note the wider context of significant financial constraints for the SDHB over a long period of time, maybe twenty years, and that the Commissioner was primarily put in place, we have been told, because the DHB was not living within its budget.

It has been long recognised that the public health system faces almost limitless demand and that choices need to made in how we spend the health dollar. Consequently we have budgets, prioritisation schemes, and lists of conditions that are not catered for in public hospital eye departments. Generally public medicine works on the basis that a department is given a budget and has to make do with it through rationing and prioritisation processes, and this certainly appears to have been the situation with ophthalmic (eye) services in the SDHB.

Due to its nature, acute medicine always gets funded. As a society we have other high priorities: treating cancer, performing life-saving surgery, treating serious childhood illnesses, and so on. Most of our cases involve chronic ocular (eye) diseases that untreated or undertreated cause blindness, but for which we have highly effective (and not particularly expensive) treatments that preserve vision. We feel that adequately funding patient care to prevent avoidable blindness should be a high priority for all health services. There is a literature showing that individuals rate loss of vision near the top of disabilities they wish to avoid[4]. Patients with eye disease often are otherwise fit, well and active, and other studies show the economic benefits of preventing blindness, or alternatively, the financial costs to society of people going blind[5].

DHBs up and down New Zealand have been struggling with this issue due to the rapid increase in numbers that need to be fitted in to eye clinics following the advent of Avastin (and other similar drug therapies) a bit over ten years ago, discussed more fully below, and other factors like the aging of the population, and increase in numbers with diabetes. Clearly the first step is to try to quantify this demand. SDHB has recently started to do this, but has a distance to go. The other side of the coin is that eye departments need to do things smarter and to be more efficient. In Dunedin a lot of effort has gone into this, although there are still measures that should be considered such as rapidly training and instituting nurse Avastin injectors. While we did not visit the site, based on information we received in interviews we suspect that there is still a lot of potential in Invercargill for increases in efficiency.

[4] For example, a 2014 poll commissioned by the US Alliance for Eye and Vision Research (AEVR), found that Americans across racial and ethnic groups describe losing eyesight as potentially having the greatest impact on their day-to-day life — more so than other conditions, including loss of memory, hearing and speech. Blindness ranked among the top four 'worst things that could happen to you' for all respondents, alongside cancer, Alzheimer's disease and HIV/AIDS.

[5] One such is the recently published Deloittes/Macular Degeneration New Zealand report *The Socioeconomic cost of macular degeneration in New Zealand*.

A. Assessment of Serious Adverse Event (SAE) Cases

We were asked to review thirty SAE cases that occurred in the year to June 30th 2016 and a further four that occurred in the first quarter (July to September) of the current year, making a total of thirty four cases. Ten of these cases were from Otago and twenty four from Southland. In all the cases the issue was that it appeared that harm had come to the patient because of delay in the patient being seen. In most cases patients with chronic disease were not seen for follow-up within the time period requested by the clinician who had seen them at an outpatient consultation. In two cases delay occurred because referrals to the service were lost. One further case is complex with a number of factors including delay involved.

An *Incident* is defined as any event that *could have* or *has caused* harm and an *Adverse Event* is an Incident that *has caused* harm. A SAE is an adverse event that when scored according to the New Zealand Health Quality and Safety Commission's Reportable Events Policy and Severity Assessment Criteria tables is recorded as Severity Assessment Code (SAC) 1 or 2 i.e. Severe, Major or Moderate harm events[6,7].

We were not convinced that all the reported incidents we reviewed did cause harm. It needs to be noted however that there are very clear recommendations for appropriate periods of review for patients with common chronic eye conditions such as diabetic eye disease, glaucoma and wet Age-related Macular Degeneration (AMD) based on large studies and extensive international experience in managing these common conditions. One example is the *NZ National Diabetes Retinal Screening Grading System and Referral Guidelines*, in glaucoma the most relevant for us would be the *2010 Australian NHMRC Guidelines into the Management of Glaucoma*. Numerous recent high quality clinical trials give clear timelines for appropriate review of patients undergoing treatment for wet AMD. The cases where we did not feel that an SAE had unequivocally occurred are still of great concern because there was generally a real risk of loss of vision due to marked delay in the patient consultation.

A disclaimer: with thirty four cases to review, in addition to reviewing the services in both centres, underlying causes of the delays, and assessment of responses to this problem, the reviewers could only review cases based on the written clinical records. When these were incomplete, effort was made to get fuller records, but obviously we may have an incomplete picture in one or two cases. We did not interview any patients.

[6] http://www.hqsc.govt.nz/assets/Reportable-Events/Publications/Reportable-Events-Policy-Final-Jan-2013.pdf
[7] http://www.hqsc.govt.nz/assets/Reportable-Events/Resources/SAC-Matrix-1-July-2013.pdf

[redacted]

In the remaining thirty two cases the harm cited was loss of vision in one or both eyes. We felt that unequivocal harm due to delay in patient review occurred in twenty-one of these thirty-two cases, i.e. we were not convinced that eleven cases involving visual loss were SAEs[8]. In summary, we felt that twenty-three of the thirty-four cases we studied occurring over the fifteen month period were SAEs, fifteen occurring in Southland and eight in Otago.

We did not feel that some of the incidents put forward as SAEs were so because the deterioration in vision seen was within the range that can be observed in that particular eye condition with appropriate follow-up timing. In other cases subsequent care restored vision, so that the patient suffered only a temporary loss of vision. A third group is where a new, serious eye condition developed during delayed follow-up: because this new problem was unrelated to the reason that the patient was having regular eye examinations, and because glaucoma is frequently not detected and patients do not present with it, it seemed to us that it was inappropriate to label these cases as SAEs. In other words, delays in follow up after cataract surgery or for diabetic review cannot be blamed for vision loss that arose from newly developed glaucoma or wet macular degeneration.

It is clear that a culture of reporting incidents has developed in the DHB ophthalmic (eye) service, and this can only be commended. We understand that the quality role in the DHB was re-scoped quite deliberately to focus more on quality improvement and patient safety, and that during the implementation of the *Safety1st* tool there was a 'Speak Up for Patient Safety and Just Culture' promotion which resulted in a significant increase in incident reporting. This readiness of SDHB clinicians to report incidents has resulted in the number of SAEs being identified and the size and scale of the problem beginning to be fully appreciated. We note that it is unlikely that other centres have the same level of clinician reporting so that problems may be better defined at SDHB than elsewhere, and that the number of SAEs is not necessarily an indication of the relative magnitude of the problem compared to other DHBs. The fact that

[8] Details of these incidents appear in the Appendix.

subsequently we have not labelled all cases as SAEs is not intended in any way as criticism of the clinicians who reported the cases. In most of the cases we did not consider met the criteria for SAEs there was significant risk to the patients of vision loss.

Looking at the twenty-one* incidents we agree meet the criteria of SAEs involving loss of vision, the striking finding is the range of eye conditions involved:

Proliferative diabetic maculopathy	7 cases
Glaucoma	6
AMD (macular degeneration)	3
Corneal graft failure	2
Diabetic maculopathy	1
Central retinal vein occlusion	1
Pterygium recurrence	1
Herpes zoster keratitis	1

*One patient had two diagnoses.

Many patients suffered marked loss of vision. Nine eyes ended up with 'Counting Fingers' or worse vision (very low levels of vision where virtually nothing useful can be seen). Three of these eyes had previously had excellent vision, 6/7.5. Another five had only moderate vision impairment before the delay in follow up, with visual acuities of 6/12 to 6/24.

Visual acuity, the most important way we measure vision, reflects a comparison against normal vision. The first number is the distance in metres from the chart that the patient stands (6m), the second number is how well the patient could read when they were standing at 6m compared with a normal person. Thus 6/12 means a patient at 6m could only read as well as a normal person would be able when they were standing 12m away. Normal vision is 6/6 (previously, in feet, 20/20). You need 6/12 vision (using both eyes) to drive. The World Health Organisation regards vision of 3/60 or worse (both eyes) as being 'blindness'.

In attempt to summarise the visual disability arising from the twenty one patients suffering adverse events relating to vision loss, we classified them as follows with regard to the consequences of the patients' delayed medical assessment:

Could have caused harm, but no visual acuity loss	4 patients
No visual acuity loss but high risk of harm	2
Relatively minor vision consequences	1
Moderate loss of visual acuity from delay	6

Major loss of visual acuity from delay	8
Inadequate information in notes (one patient appears twice, relating to each eye)	1

Most of the patients where SAEs occurred without documented loss of visual acuity were diabetics who developed proliferative diabetic retinopathy, abnormal blood vessels growing into the eye; a very serious condition that untreated has a high progression to blindness. Other cases of marked deterioration in the visual field had loss of vision, but not of visual acuity.

Delay in patients being seen in thirteen out of our twenty three cases was due to patients being lost to follow-up. Patients were seen after they contacted the ophthalmic (eye) service (in some cases after repeated attempts), or were referred back. In two patients delay occurred because referrals to the ophthalmic (eye) service were lost (lost twice in one case). One of these cases also suffered delays after being first seen. The seven patients who suffered from delayed booked appointments waited from two times to ten times the period the doctor had requested (average 4.4 times the requested interval). In one case we did not have enough information to draw a conclusion.

Appropriate patient follow up appointment timing for the medical conditions covered by these cases, to minimise undetected major disease progression, is extremely well established. In a busy public ophthalmic (eye) service inevitably there will be some delay to follow-up with some patients. Delay of up to 1.5 times the requested review period (e.g. patient is booked for 6 months but seen at 9 months) is probably acceptable, delay stretching out to twice the requested interval is not. In the patients not lost to follow-up we observed much longer delays than this, as outlined in the previous paragraph, up to ten times the requested review period.

In case 40394 delay was a factor but a number of issues combined to create the adverse outcome, outlined in the SAE report for this incident. With respect to this case, we would reiterate that gonioscopy (examining the drainage angles of the eye for angle closure, which requires different specific treatment) must be performed in the work-up of all glaucoma cases, and glaucoma patients should not be dilated until gonioscopy has been performed, because this prevents accurate gonioscopy, and may in the pre-disposed, actually trigger acute angle closure glaucoma. It is therefore not appropriate to dilate all patients coming to a glaucoma clinic. This case also highlights the danger of doing tests in isolation: the patient had a visual field test performed that showed significant disease progression, but this test was not viewed by a clinician. If any medical test is performed, be it blood test, biopsy, or in the ophthalmologic context, visual field test or OCT (optical coherence tomography) scan, the test result must be studied by the responsible clinician shortly after the test has been performed, so that serious findings are discovered and can be addressed in a timely manner. In the ophthalmic context, ‘shortly after’ can be taken as within two or three weeks for most tests, but sooner for patients with wet macular degeneration.

In Southland we are aware of five patients who were lost to follow up who called the ophthalmic (eye) service multiple times unsuccessfully trying to get appointments. Others we know of with delayed appointments had the same experience, and we suspect that in other cases this occurred but has not been documented. Calls were generally not handled by clinical staff, and were not followed up with reference to the clinical record. Even medical practitioners had great difficulty contacting clinical staff in this department (e.g. Dunedin ophthalmologists).

In summary, we did not agree, on the information we had available, and with the passage of time, that eleven of the thirty four cases were in fact SAEs. A number of cases developed vision threatening disease without losing significant vision. However fourteen patients suffered moderate or major loss of visual acuity directly attributable to delay, and two additional cases involved significant delay in managing malignant disease, with risk to patient life. Many patients were lost to follow up. In Southland many of these patients tried to contact the service to get appointments, but lack of an adequate telephone answering system meant that they were unsuccessful. Patients who *were* seen following booked appointments faced huge unacceptable delays in being seen (being seen on average more than 4 times the review period requested). We also reiterate that the eleven cases we do not consider meet the criteria for SAEs still include examples of unacceptable delays.

B. The wider picture: Forces working against ophthalmology

It is important to emphasise that some of the challenges that the ophthalmic (eye) services in Otago and Southland have experienced in relation to resourcing are not unique. Up and down New Zealand ophthalmology faces similar specific problems when it comes to getting adequate resourcing. Ophthalmology is not a high profile specialty like medicine, general surgery or anaesthesia, and ophthalmologists are rarely part of the hospital or DHB executive decision making 'inner circle'. This problem is exacerbated by the fact that most ophthalmology is carried out in isolation in the eye outpatient clinic: ophthalmologists interact with other medical and surgical specialties far less than is the case for most hospital specialists — most eye patients are otherwise fit and well. We get the impression that a barrier to adequate resourcing is relatively limited understanding by senior management and by medical colleagues from other specialties as to what ophthalmologists actually do. Ophthalmology is seen as a surgical specialty, and the surgical model is that patients are referred with a problem, have a surgical procedure, and then once recovered from surgery are discharged.

Ophthalmology is in fact predominantly a medical specialty, and the majority of an 'eye surgeon's' time is spent in clinic treating patients with chronic conditions who rarely go near an operating theatre. A typical ophthalmologist will do only two theatre lists a week. Glaucoma, diabetic eye disease, macular degeneration, and childhood squint and amblyopia are very common disorders (and there are others): for instance glaucoma affects 3% of the population 49 years and older,

all diabetics need some sort of eye health/ophthalmic monitoring, and those with more than minor diabetic retinopathy (a huge group), need to be seen by an ophthalmologist at least annually.

Ophthalmology (eye) service delivery and workload management has not been helped by the current Ministry of Health requirements (with financial penalties) for DHBs to fulfil the seven Elective Services Patient Flow Indicators (ESPIs). Service delivery has been particularly distorted by ESPI 2, that new referrals must be seen within 4 months, and by ESPI 5, that patients booked for surgery must have their operation within 4 months. There is no ESPI relating to reviewing patients with chronic disease in a timely manner. The direct result has been that in order to meet these two ESPIs, new patients have been prioritised over follow-ups, and surgical lists over outpatient clinics, further adding to the problem of follow-up capacity and back logs. Interestingly, SDHB ophthalmology has been very 'good' at meeting the ESPIs: consequently the message to senior management has been that all has been well in this regard, and this may have masked management awareness of the severity and seriousness of the needs and performance in terms of follow-up of patients by the two ophthalmic (eye) services.

Across New Zealand over the last ten years ophthalmology (eye) services have faced a combination of issues that have hugely increased demand for outpatient clinic time. The predominant factor has been the arrival of anti-VEGF therapy, which in New Zealand mostly involves injection of the drug Avastin into the eye. This treatment has allowed us to successfully reverse vision loss and prevent blindness in patients with wet age-related macular degeneration (AMD), the number one cause of blindness in New Zealand, causing about 50% of blindness, which was previously untreatable. Avastin therapy requires semi-sterile procedure and for wet AMD must be performed every one to three months generally for the rest of a patient's life. Avastin also has a major role in managing diabetic eye disease, and other conditions such as retinal vein occlusions.

Other factors have also driven up demand for eye clinic consultations at a much faster rate than natural growth:

- Demographic change and the aging of the population. Eye problems predominantly affect the older age groups, for instance glaucoma occurs in 0.4% of those in their 50s but in over 11% of those over 80[9].
- Increased rates of detection of glaucoma and angle closure.
- Increases in numbers with diabetes.

Different DHBs have responded in varying ways and at varying times to this 'perfect storm'. The Southern DHB is by no means the only DHB struggling to cope with the increase in workload, but the scale of the problem as revealed by

[9] Blue Mountains Eye Study, Australia.

the Acuity Tool data does suggest that things are considerably worse here than in other centres.

The Acuity Tool was designed to visually represent the scale of the problem of overdue appointments. In brief the Acuity Tool compares the actual patient wait for an appointment to the period requested by the doctor who most recently reviewed the patient: i.e. six month review requested, waiting for 18 months equals 'Acuity' of 3. As a rule of thumb, a patient wait of twice what has been requested is in the authors' opinion unacceptably long: the Acuity Tool however labels waits of 2 to 3 times booked time as 'low risk', and only waits of five times the booked time and longer as 'high risk'. Ophthalmologists choose the period until a patient next needs to be seen based on well-established protocols[10] designed to avoid patients coming to harm: it may not be intended, but the Acuity Tool appears to suggest that these are wrong, and that in fact patients can safely wait three or four times longer than has been requested by their consultant. This is of serious concern to us.

The Acuity Tool is very useful in monitoring the extent of the problem with overdue patients and should be retained for that purpose, but is a very limited tool in managing clinical risk. It is not a solution to prioritisation and excess demand.

The SDHB clearly has shown good understanding of these wider ophthalmic issues over the last couple of years, and has been very active in response to them over this period. The root causes of the SAEs we studied however go back decades, and we feel that the above general comments that probably apply to most if not all DHBs are relevant to the lack of capacity in Dunedin and Invercargill that lead to our adverse events.

C. Raising the alarm, and the management response

We are investigating a large group of SAEs that occurred in the fifteen months from July 1st 2015 where patients came to harm because of delay in having ophthalmic medical consultations. It is clear however that this is not a newly arising problem, but is rather the culmination of insufficient responses by senior management to growing demands for ophthalmology (eye) services over many years. We were concerned that one possibility could have been that these issues were not adequately flagged to senior management by the ophthalmic workforce, in particular by the ophthalmologists. However this was not the case in Dunedin. There is also evidence over more recent years that the problems in Invercargill were raised on a number of occasions. The Timeline gives examples from a long series of documents that we have seen.

We consider that staff from the ophthalmic (eye) services did attempt to communicate their concerns regarding the growing problem to management. These efforts were made in multiple ways, but while management appear to have

[10] Discussed above in the section *Assessment of Serious Adverse Event (SAE) Cases*.

got the message that follow-up patients were not being seen, this message was from 'not the only group of clinicians or service raising concerns about resources' and in the context of a DHB under financial pressure: 'with the financial situation the way that it is, you have resources compared with others'. As a result the scale of the response needed was not realised, and management did not appear to understand that the concern was that patients were losing vision because they were not getting treatment within evidence based timeframes.

In terms of management response, it is not possible in hindsight for us to be certain about how seriously the problems were understood or being taken by management at different times. Clearly Invercargill has long been a concern because of the lack of consultant ophthalmologists. The Directorate Leadership Team (DLT) told us that 'an intensive programme of investigation into the service' began at the end of 2013 in response to concerns raised by SMO 6 (see timeline). It appears that this investigation eventually enabled the size, shape and accumulation of the problem to be more fully appreciated and understood. For example it was realised that there were also major capacity issues in Dunedin, which it appears had not been appreciated despite numerous communications to this effect over the years. It also appears that it took until late 2014 for the management to fully appreciate the clinical risk (during interviews in December 2016, we were advised that they, the (DLT) 'became aware of the issue [the size of clinical risk] late 2014' and that 'concerns [in relation to this] were only raised over the last 18 months'). In addition the five SAEs in Southland were reported late 2014. We are concerned that it appears that the SAEs triggered this phase of action, rather than reporting of problems by SMOs through the approved channels over years.

When efforts to increase funding, staff and capacity have been declined, there does not appear to have been any assessment of the risk consequent from such decisions, and the opportunity to identify the problem, and that it was being compounded, was missed at these decision points.

Around October 2014, presumably in response to the five Invercargill SAEs reported on in January 2015, ophthalmology does seem to have been more fully appreciated and taken seriously by senior decision makers, and we note the extensive efforts to remedy the situation subsequently. The fact that this review is being held, and the extent to which we were supported, are also witness to a very changed attitude. We do retain concerns however that there is a perception that the problems in Invercargill have been sorted out, and that Dunedin is well on track to solutions: this is premature.

We in particular are concerned that the message that a quantum change in ophthalmic capacity is needed, rather than a tidying up of existing processes, has yet to be fully grasped.

D. Lack of capacity

The over-riding reason why patients were not seen when they should have been was because the two eye departments lacked capacity to meet the demand for their services: the clinics did not have enough appointments for the patients they had to see. Capacity refers not just to health professionals, in our context specialist ophthalmologists, other doctors, nurses, optometrists and orthoptists; but also to physical space, especially clinic rooms, to equipment, and to clerical support staff.

Preventing blindness should be a priority for DHBs and should be adequately funded. The traditional DHB planning and funding approach i.e. funding based on the historical situation plus a bit more, was not able to match the sudden, game changing impact of increased patient volumes resulting from the introduction of Avastin as a treatment. Avastin created a large amount of high priority extra work: so doing some (but not enough) Avastin treatments on the same or an insufficiently increased budget and limited capacity resulted in other work previously done no longer being able to be done.

As outlined earlier, the introduction of Avastin treatment for wet macular degeneration (plus other diseases such as diabetic maculopathy) is a major factor but not the only one. Increases in the diabetic population and demographic changes such as glaucoma and cataracts which primarily affect the growing elderly population also contributed to the rapidly increasing patient volumes. These large increases in workload over the past 10 years have not been matched by timely funding and resourcing. Almost certainly, this occurred on a background of under-funding/mis-match between service levels and need, before the Avastin 'storm' arrived.

We had hoped to look more fully at the increases in workloads in the two departments over the last ten years, but there have been difficulties supplying us with this data.

The problem of capacity in Invercargill was compounded by long-standing problems recruiting and retaining ophthalmologists in Invercargill. There was a period when there was no senior medical officer based at Invercargill and the department was led by the Clinical Nurse Specialist. This problem improved after the recruitment of SMO 4 in November 2011. The problem of capacity in Dunedin was compounded by a 4 to 5 year period up to 2010 of difficulty recruiting and retaining ophthalmologists, also over recent years, problems recruiting and retaining orthoptists and optometrists.

Progress was made in Invercargill when the department moved into its current location. We did not visit the site and so note that there may be deficiencies that we did not elicit during our interviews with staff. We did visit the Dunedin department. There are plans for a new building including a new ophthalmic (eye) department in Dunedin at some stage in the future, however in our opinion changes to the current space are needed urgently. We found the Dunedin clinic to

be cramped in terms of physical space; there were not enough clinic rooms, little privacy, clinic rooms were poorly laid out and there was a lack of modern equipment such as dental chairs which would be considered standard in a modern eye department. We were told that machines in the department overheat due to lack of adequate air flow.

Despite all this we were impressed with the team spirit and commitment to the department shown by all the clinical staff in Dunedin. By contrast there has been rapid turnover of clerical staff in Dunedin and very poor morale among administration staff. They are required to work in a very physically cramped space. A new but temporary administration team leader role has been implemented — March 2017: we have been informed that this role is now permanent.

The lack of capacity has also not surprisingly resulted in stressed staff, disgruntled patients, and tragically the SAE cases under review. This manifested in the poor morale in administration staff as described above. We were advised that concerns have been raised by nursing staff with their union. Medical staff have expressed concern about medico-legal exposure.

It is well recognised today that the demands on eye services cannot be met by a specialist-only (i.e. ophthalmologist only) service. Ancillary clinicians such as optometrists, orthoptists, non-specialist medical staff, appropriately trained nurses, and sometimes appropriately trained ophthalmic technicians need to be used, but they need also to be supervised by consultant ophthalmologists. In practice for systems like this to work you need multiple clinic rooms: both SDHB sites are really handicapped with regard to recruiting ancillary staff by their very limited numbers of clinic rooms.

Efficiency is very important in an eye clinic: an efficient clinic can provide quality care for far more patients in a given time than an inefficient one. Efficiency depends on systems, and having the right staff doing the right tasks. For instance it is a waste to have registered nurses primarily ushering patients around a department and performing visual acuities: this work can be done by Health Care Assistants. Efficiency above all depends on a well laid out eye clinic with good patient flows: both sites are handicapped by a lack of this.

Both sites have made efforts to build an ophthalmic team, and we do note problems in finding optometrists and orthoptists to work in the departments. Heavy focus needs to be placed on involving non-specialist staff. One example is that there should be fast-tracking of training of nurses to perform Avastin injections. In Counties Manukau DHB for instance the nurse injector will treat 30 patients in a half day: this service is willing to provide assistance in developing a rapid path to train nurses to fulfil this vital role.

E. Lack of a clinical prioritisation system

The two departments do not appear to have operated with a system for prioritising patients beyond the medical ‘see in (time period)’ request when a

patient is seen in clinic e.g. 'see in two months', and in some cases 'must be seen', more recently in Dunedin known as 'live'. This becomes insufficient when the demand/volume of booked appointments required greatly exceeds the number of future appointments available.

For some time this problem of not enough available appointments was 'managed' by administration staff, who were not qualified to, nor had set processes for, deciding which patient should get priority. This is unacceptable. In Dunedin the system of 'live' appointments to prioritise the most urgent follow-ups, has been effectively 'grid-locked' by all patients being prioritised as urgent in an attempt to avoid patients waiting excessive amounts of time or getting lost in or by the system.

The introduction of the Acuity Tool has been excellent at quantifying the number of patients waiting for follow-up appointments and quantifying the time beyond that requested that they have waited.

In brief it provides a very useful snapshot of how much the system is not coping, if interpreted correctly. However we have strong concern that the Acuity Tool implies that wait times well in excess of the recommended evidence based guideline time period are 'low/no risk'. The Acuity Tool uses Red (>5x requested review period) to denote 'High Risk'. Yellow denotes 'Medium Risk' which is defined as waiting between three and five times the requested time for an appointment. (There is also Pink for Low Risk and Green for being seen on time.) We consider that delays of more than 1.5 carry significant clinical risk and that these Acuity Tool classifications are quite frankly misleading.

As stated earlier appropriate patient follow-up appointment timing for the medical conditions covered by these cases, to minimise undetected major disease progression, is extremely well established. In a busy public ophthalmic (eye) service inevitably there will be some delay to follow-up with some patients. Patients also cancel and postpone appointments or for all sorts of reasons do not attend booked appointments. Delay of up to 1.5 times the requested review period (e.g. patient is booked for 6 months but seen at 9 months) is probably acceptable, delay stretching out to twice the requested interval is not.

Waiting > 5 times the requested follow-up is huge, and indicative of a service really not coping. It seems to have taken the DHB time to recognise this. Clinicians for a long time however have been aware that they bear some of the responsibility if patients are not being seen in a timely manner. Concerns were raised (see Timeline) and efforts for change initiated but often not progressed. Also to some degree a culture of tolerance of unacceptable delays developed because this was the norm. There was considerable stress placed on the eye department staff, particularly on the Clinical Leader, when it could be seen that there were dangerous delays in patients being seen, this was being flagged to management, but nothing was happening. In the patients not lost to follow-up we

observed much longer delays than this, as outlined in the previous paragraph, up to ten times the requested review period.

Ultimately the departments continue to lack a system to prioritise high risk patients that is effective. The 'live appointments' system has resulted in a gridlock. We cannot believe all patients currently being seen by the departments are highest risk, although do recognise that due to capacity limits lower risk patients have been turned away from the services for many years. No routine referrals have been seen in the Dunedin department for 10 years: e.g. lower risk glaucoma referrals, vision threatening pterygium, often semi-urgent referrals also have not been seen.

Prioritisation schemes often use a 'traffic light' classification similar to the Acuity Tool but based on clinical assessment of the individual patients: 'red patients' are patients who must be seen in a timely way because of the risk of serious consequences such as loss of vision if they are not seen in a timely manner. 'Green' patients have sufficient ophthalmic disease to require regular review, but are not in imminent danger. 'Orange' patients are of intermediate risk. Tight time frame limits are set within which the red patients must be booked, more lax time frames are set for the orange, and the green are fitted in as they can be (but clinics must routinely contain some green patients). We would recommend that the SDHB ophthalmologists at least set up criteria for 'red' patients in the major disease groups, and label these patients.

F. Lost referrals and requests for follow-up

In many of our cases in both centres patients were not seen because referrals or follow up requests for appointments were lost in or to the system, which just should not happen. Attempts have been made to remedy these systemic faults. In April 2010 a box of unprocessed follow-ups dating back to 2006 had been found in a cupboard. These were reviewed and actioned, however in November 2010 there was concern expressed again that another 'cupboard' was potentially being created. As stated above, for some time the problem of not enough available appointments was 'managed' by administration staff, who were not qualified to, nor had set processes for, deciding which patient gets priority.

It is essential that the service have in place a robust auditable process for tracking and accounting for all referrals and requests for follow up ('blue slips'). Due to time constraints we were not able to fully investigate whether this has been instituted, but do recognise that the problem has been identified in both centres.

Attempts by patients to find out about or get an appointment are described in complaints and SDHB review reports. In one case a patient presented to the clinic and refused to leave until seen, after multiple attempts to phone unsuccessfully. It was clear to us that contacting the Southland eye department by phone has been a problem. For a period calls were not necessarily recorded,

and if recorded this was not systematic. Calls were not referred to clinical staff and did not result in action.

Patients under the care of an Eye Department need to be able to have unobstructed phone access to clinical staff. This can prevent loss of vision for some groups of patients: patients who have had recent surgery (risk of endophthalmitis), patients who have had corneal grafts (graft rejection episodes need to be treated promptly), patients who have had trabeculectomies (risk of bleb infections), patients with advanced diabetic eye disease, patients at risk of retinal detachment, patients with iritis etc. It is also very important for other groups of patients, for example, glaucoma patients on medications at risk of drug side effects, patients lost to follow-up.

Currently Invercargill callers must go through the main hospital call centre and then be put through to the department. Calls are answered by administration staff who then determine how to deal with them and to whom they should direct them. If nurses take the call, this is recorded in a log. In Dunedin a direct line is available and is answered by a nurse. An answer phone records any unanswered calls and the nurses check for messages 2–3 times each half day. Nurses log all calls and note relevant information in the patient's clinical record. This is a much more robust system and we consider it essential that Southland implement a DDI phone line and standard process in Invercargill as per Dunedin.

G. Governance and culture

The two sites are physically isolated from each other (a 2–3 hour drive) and were originally within two different organisations (Otago and Southland DHBs). When the SDHB was first formed, they continued to function as two different entities, and in many ways this continues today. The departments have different systems and ways of working and have had different management structures. Department managers have had many areas of responsibilities and no ophthalmic background. The complexity of ophthalmology has not been fully understood by managers with no background in the specialty and there has been mistrust. Responsibility for management of the departments day to day is spread among a number of individuals which can be confusing, and there are real gaps, e.g. day to day staff management in Dunedin. In Dunedin management of the department is split between a Unit Manger and a Service Manager, in Invercargill between a Unit Manger, a Service Manager and a Nurse Manager.

Lines of communication between the various Southland managers and the Clinical Leader appear to be poor: the Clinical Leader advised us that some decisions are made and actions taken without the Clinical Leader's knowledge or involvement e.g. outsourcing of cataract work to Southern Cross in Invercargill. Efforts to standardise or effect change with the aim of increasing efficiency across the two services have not always been adopted and in some cases have been resisted. It appears that the Clinical Leader only infrequently visits the Invercargill department.

We believe that an underlying cause for the problems we have identified in the past has been deficiencies in governance of the two departments. Administrative and nursing staff have not been supervised, and managers responsible for the departments have been distant, have lacked ophthalmic backgrounds, and have had too many other areas of responsibility to really be on top of what has been happening in the ophthalmology (eye) service. Having said this, we were impressed with the current managers' grasp of the issues and determination to try and effect necessary change. We do note however that the Unit Manager in Dunedin is shortly to take on responsibility for orthopaedics outpatients and the fracture clinic as well as her current responsibilities for ophthalmology, ENT, rheumatology and neurology, which must further weaken day to day management of the ophthalmic (eye) service.

H. Inefficiencies in Invercargill

SMO 2's visit and report of April 2015 highlighted inefficiencies in the Invercargill department systems, low numbers booked into clinics, and unnecessary repetition of tasks. In some clinics markedly fewer patients were seen than would be expected, e.g. cataract surgery preparation nurse clinic seeing two patients in a three hour period. Refilling repeat prescriptions for patients which involves considerable time of various staff is not a service that needs to be provided at hospital level, elsewhere patients are directed to their GPs for this. Clearly a lot of effort has been put in to improving systems in Invercargill subsequently and we understand that efforts have been made to address problems identified at this visit.

However based on what we were told in interviews, we suspect however that there is further room for improvement. Invercargill clinic volumes need to be monitored closely and bench marked, for example in the Dunedin Avastin clinic in a half day the registrar does 21 cases plus walk ins, in Invercargill the GP injector does 8 to 11 cases in a half day. (In Manukau the nurse injector does 26 to 30 cases in a half day, the key to high volumes is that the nurse works with the support of one or two other nurses).

There was a period when Invercargill had no ophthalmologists on staff and the Clinical Nurse Specialist (CNS) had to run the service by herself, with only intermittent ophthalmologist presence. We acknowledge her hard work maintaining the service in this very difficult situation. It seems however that systems and processes developed at that time and appropriate to those circumstances in some cases continue today. Fortunately the situation has changed, Invercargill is now well supplied with permanent ophthalmologists and systems and processes need to change too. We are concerned about suggestions of inefficiencies, friction, and resistance to change and leadership decisions. Responsibility and accountability for decision making needs to be clear and adhered to by all staff. We must repeat that we did not visit the department, but the above conclusions arise from comments made by at least three individuals.

We note that during the feedback process in response to our draft report a staff member raised issues of physical congestion in the clinic, risk in the event of an emergency, lack of privacy, and other concerns related to adjacent services, in the current Invercargill clinic. External review of the Invercargill department systems and processes would be useful, and the service would really benefit from formal credentialing of the two departments as is performed in most DHBs, as opposed to credentialing of the SMOs (Senior Medical Officers) alone.

Recommendations

We want to acknowledge that throughout the period we have studied that the staff and management of the two departments have been actively working to adapt practices to try and meet the demand on their services, and that since 2015 SDHB quality and management staff have been actively engaged with the capacity issue. SDHB has taken a number of corrective actions with further actions in progress or planned. Whilst SDHB has made major efforts to address the problems there is further work to do. Our recommendations are based on our assessment of the situation in December 2016 and need to be considered alongside actions already progressing.

Capacity

1. Capacity needs to be increased.

   a. There needs to be regular accurate measurement and reporting of the demand that has to be met, and current capacity at both sites, using objective agreed criteria that account for actual and projected increases in demand. This process needs to include the Clinical Leader, and sufficient service medical, nursing and administration staff as well as management and planning and funding staff.
   b. Invercargill:
      i. Measures already planned may be all that is needed but there needs to be ongoing surveillance that this is the case.
   c. Dunedin:
      i. Almost certainly needs more ophthalmologists, in particular a medical retinal specialist.
      ii. Need to fast track training and implementation of nurse/other non-specialist Avastin injectors.
      iii. Need to increase optometrist support considerably, optometrists ideally to work alongside ophthalmologists in clinics. We would caution against outsourcing work to optometrists in the community (except where this is driven by geographic isolation). The major reason is that this could prove to be a huge financial drain if it is being funded by the DHB. Early glaucoma and in particular patients who might have glaucoma involve a large section of the population, and a lot of money can be spent on low-risk individuals who will never risk

loss of vision in their lifetimes. In addition, having optometrists and other ancillary staff working alongside ophthalmologists allows ongoing training and maintenance of service quality.

iv. Need to review clinic roles. Ushering patients through the department, measuring visual acuity, and other simple tests should be undertaken by HCAs. One nurse needs to be on floor to deal with any medical issues arising with patients. Nurses otherwise should be employed only if they are performing more advanced roles.

v. Needs more clinic consulting rooms.

vi. Needs much improved clinic layout and patient flow, another (private) visual acuity lane.

vii. Clinic equipment needs updating — for instance dental chairs should be available in consulting rooms. We did not look into this issue in any detail: we would recommend that as well as credentialing the ophthalmologists, the department and its facilities undergo regular credentialing, as occurs in most DHBs.

viii. The service needs to look urgently at finding an alternative site in existing or temporary buildings, to create an eye clinic for the medium term, with careful attention to layout, patient flow, future needs and patient privacy. The issues with altering the present clinic are noted (difficult to make changes to existing layout due to asbestos), and the reality that a new building is not going to come online for quite some time.

d. Both departments need to continue to try and work smarter and more efficiently: liaison with other services in the South Island and country as a whole is to be encouraged so ideas that work can be exchanged.

e. Need to fast track recruitment. Recruitment of ophthalmologists, optometrists, orthoptists and ophthalmic technicians is challenging: there are shortages of these willing to work across the country, in particular in the Southern Region. Management needs to be able to react swiftly to expressions of interest, potential staff have been lost in the past due to management inaction.

Management of the Ophthalmology Departments

2. Both departments should have dedicated Managers, or at least Coordinators, (ideally but not necessarily with ophthalmic background, e.g. previous ophthalmic nurse), with management skills, solely responsible for running the eye department (all staffing groups including clerical/administration), to ensure that the departments are running smoothly on a day to day basis, to identify longer term needs, and to address issues as they arise such as a blow out in appointment times. This individual may be the best person to answer clinical phone enquiries (and may also do a certain amount of clinical work if this is required to make this a full time position). In an eye department ensuring adequate and functioning equipment is another important ongoing task that this person could be responsible for. This person should liaise regularly with the Clinical Leader.

Prioritisation of patients

3. A system to clinically grade patients with common potentially sight-threatening conditions priority such as the 'traffic light' system, red – orange – green needs to be implemented, and utilised in the first instance to review all patients still waiting for follow-up, and then be utilised ongoing. At minimum, SDHB ophthalmologists need to at least set up criteria for 'red' patients in the major disease groups, and label these patients. (The present arrangement in Dunedin of 'live' being red, seen on time green and others orange is not such a system.)

Patient phone access

4. All SDHB eye patients should have the ability to contact the relevant department readily. This can prevent loss of vision for some groups of patients:

    a. A direct phone line for patients to speak directly to clinical staff as per the system in Dunedin should be implemented immediately in Invercargill. Calls should go to a designated nurse with answerphone back up checked routinely 2–3 times per half day. Problem, and response, to be filed in eye records.
    b. Audit needs to be carried out to ensure that patients can readily contact both departments, that they speak to an appropriately trained person when they raise clinical concerns, that they get an appropriate response to their queries, and that this is recorded in their clinical notes.

Management of referrals and follow-ups

5. Audit needs to be undertaken to be absolutely certain that tracking systems are in place so that all referrals are responded to in a timely manner.
    a. That all patients seen in clinic have an 'outcome' recorded and acted upon.
    b. If clinic waiting lists are blowing out to, say, longer than twice the requested time (an acuity of 2), patient notes need to be triaged (see traffic light system), and patients either discharged, or extra clinics held.

Efficiency

6. Efficiency is everything in an eye clinic. Ongoing review needs to be carried out to ensure clinics are seeing appropriate number of patients, and that inefficiencies and low priority tasks have been eliminated. Standard approaches across the two departments should be encouraged.

Credentialing

7. We would recommend that as well as credentialing the ophthalmologists, the department and its facilities undergo regular credentialing, as occurs in most DHBs.

National improvements

8. At national and Ministry of Health level, we recommend:

   a. National discussion on ophthalmology priorities: avoiding blindness needs to be high on the list, patients with early disease lower on the list.

   b. National reporting of overdue appointment statistics from all Eye Departments.

   c. Establishment of systems to identify worthwhile major new health care technologies, such as the advent of Avastin therapy, in the future, so that adequate funding responses can occur in a timely way.

Sharing learning

9. The SDHB should share this report with other DHB's via their Chief Medical Officers to ensure any patient risk arising from similar circumstances is identified and controlled. This will require all DHBs to have systems monitoring overdue appointments for patients with chronic potentially vision-threatening eye conditions. There may be a role for national implementation of the Acuity Tool.

Appendix:

Incidents we did not consider met the criteria of Serious Adverse Events
(with brief explanations)

36393 vision subsequently recovered with treatment

45753 progression of glaucoma not outside normal clinical experience

40428 progression of glaucoma not outside normal clinical experience

40656 intraocular pressure control temporarily lost

43555 it is not clear that delay has caused visual loss

49253 progression of glaucoma not outside normal clinical experience

49402 significant visual loss did not occur

49408 during delay developed a new eye condition unrelated to diabetes

50949 during delay developed a new eye condition unrelated to cataract surgery

56503 vision subsequently recovered with treatment

57785 complicated history, not certain delay has caused significant visual loss"